From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/16/2020 9:09:24 PM

To: Eric Hughes [(b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6) Colvis,

Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John

(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman];

Vincent, Michael [(b) (6)

CC: Elizabeth Kim [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: UK Therapeutics Prioritization List and Process

Attachments: XYZ candidate agent list as of 4-15-20.xlsx; ACCORD product selection process 4-15-20 deid.pptx

Dear ACTIV TX-Clinical Agent Prioritization Subgroup Members,

Please see attached a slightly anonymized list of therapeutics considered by the science group in the UK that we spoke about. They have indicated their permission for us to share this with this group only, to aid in your deliberations about our parallel agent prioritization efforts, but with the express request that you not copy or distribute this beyond the group on this email. We have been asked to emphasize that this is a work in progress and does not represent the end of a considered or consolidated process, nor has that process or these results been formally adopted or endorsed by any UK government agency or organization. We will work with Deloitte to incorporate such information as you think valuable into the larger inventory of potential agents for prioritization that we have been working on with you, by the way.

FYI, we have asked for an update on the protocol that would be associated with testing such agents as may be selected, and have been told that is not sufficiently finalized to be shared yet. We will let you and the MP Subgroup know when we have something to share there.

Thank you all for your help in adhering to our collaboration guidelines from that team.

Kind regards, Stacey

Stacey J. Adam, PhD Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

Sent: 4/15/2020 7:46:21 PM To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melenciocl Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups I just sent out the same message with these names now in the bcc line. So everyone will have received it now. From: Parker, Ashley (NIH/OD) [E] < (b) (6) Sent: Wednesday, April 15, 2020 2:08 PM To: Collins, Francis (NIH/OD) [E] <coll Melencio, Cheryl (FNIH) [T] < (b) (6) (b) (6) Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups Francis - the following emails were missing from the list that went out, please see 8 emails listed below. Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone. Disbrow, Gary (OS/ASPR/BARDA) (b)(6)Kim, Elizabeth <el (b) (6) Marston, Hilary (NIH/NIAID) [E] < (b) (6) Paul, Steve < (b) (6) Payne, David <david.j. (b) (6) Plump, (b)(6)Santos, Nancy (b) (6) Shen, Yuan Li (FDA/CDER) < (b) (6) Thanks, Ashley From: Collins, Francis (NIH/OD) [E] < (b) (6) Sent: Wednesday, April 15, 2020 11:39 AM To: Melencio, Cheryl (FNIH) [T] Parker, Ashley (NIH/OD) [E] < (b) (6) (b) (6) Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one? From: Melencio, Cheryl (FNIH) [T] (b) (6) Sent: Wednesday, April 15, 2020 11:19 AM To: Parker, Ashley (NIH/OD) [E] (b) (6) >; Collins, Francis (NIH/OD) [E] (b) (6) Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups Austin, Christopher (NIH/NCATS) [E] >; Bright, Rick (b) (6) >; Collins, Francis (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (NIH/OD) [E] (b) (6) >; Corey, Larry (b) (6) >; Erbelding, Emity (NIH/NIAID) [E] . Dolsten, Mikael (b) (6) (b) (6) < Fauci, Anthony (NIH/NIAID) [E] (b) (6) Frankowski, David (b) (6) Hudson, Thomas < : James, Stephanie (FNIH) (b) (6) (b) (6)

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

From:

Marks, Peter (FDA/CBER) (b) (6) Mascola, John < (b) (6) Meeker, (b) (6) ; Pangalos, Mene < Paul, Steve (b) (6) >; Perlmutter, Ro (b) (6) ; Rasi, Guido	/>; Marston, Hila	ary (NIH/NIAID) [E]		(6)
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Desrosiers , Betsy (b) (6)	Dickens, Jim	(NIH/NCATS) [C]	(b) (6)	>;
Doroshow, James (NIH/NCI) [E] < (b) (6)	: Goff, Dav	id (NIH/NHLBI) [E]	< (b) (6)	Heaton,
Penny < (b) (6) King, James				
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Woodcock, Janet (FDA/CDER) < (b) (6)				
Sam (NIH/NCATS) [E] (b) (6) Bud	chman, Tim (OS//	ASPR/BARDA) (CTR	(b) (6)	
Butterton, Joan (b) (6) De	Claro, R. Angelo	(FDA/CDER)	(b) (6)	
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Cheryl Melencio Administrative Manager, Research Partnerships

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria (JRDUS); Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]

Optional

Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

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		ID) [E]; Roa R/BARDA) (a; (t	6) (6)	Kim, Pete	er (NIH/NIA	(ID) [E]; Jo	nathan	Li; Marks,	Gilbert	
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Optional Attendees:						Jonathan; E ijay Nirula; I						na noa;
Dear ACTIV	-2 Writi	ng Team	7									
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Please see th	e sugges	ted attacl	hed ager	da. Ple	ease let	me know	if you ha	ve additi	ions or	amendm	ents.	
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To:

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner [Jacqueline.Kirchner@gatesfoundation.org] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Kurilla, Michael (NIH/NCATS) [E] el Jansen, Kathrin (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary [(b) (6) (b) (6) Butcher, Tina Demarcus [Melencio, Cheryl (FNIH) [T] (b) (6) Macone, Erin (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan ; Tolman, Brett Alvarez, Rosa (b) (6) (b) (6) (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d); Dana Carluccio (b) (6) Rose Li Central Account [Anderson, Margaret [(b) (6) (b) (6) Smalldon [Stratton, Benjamin | (b) (6) (b) (6) Mollica, Linda /US [Qashu, Felicia (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. Wung, Peter /US [Hoots, W. Keith (NIH/NHLBI) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm); Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa] Subject: ACTIV Therapeutics-Clinical Working Group Meeting #10 Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide 20200611_Final.pdf Location: https://fnih.zoom.us/j, (b) (6)

Start: 6/11/2020 5:00:00 PM End: 6/11/2020 6:00:00 PM

Show Time As: Busy

Required Attendees:

Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Coilins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (

Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E], Jacqueline Kirchner

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michae (NIH/NCATS) [E]; Lowy, Douglas (NCI), Young, John, Biggs, Mary; Butcher, Tina, Demarcus; Macone, Erin, Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Tountas Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L Central Account; Anderson, Margaret; Lucas Smalldon;

Stratton, Benjamin; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (b) (6) (NIH/NHLBI) (E); Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) (E); Chen, Helen Q.; Wung, Peter /US;

Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]

Dear ACTIV Therapeutics-Clinical Working Group Members,

Please find attached the slides, which include the agenda for today's meeting. We are looking forward to speaking with you all today.

In addition, just a reminder for those who might need it/be interested in sharing please find below the link to the agent survey to use for submission of an agent for consideration for prioritization.

Complete Survey Here: ACTIV COVID-19 Clinical and Preclinical Candidate Compound Portal

Thank again to all for your continued participation in this effort.

Best, Stacey

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US (San Jose) US (San Jose) US (Tacoma)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: https://fnih.zoom.us (b) (6) From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 4/15/2020 6:08:29 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryi (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: RE: List -- just copy and paste in occ. lists of April 3 plus working groups Attachments: Master list for ACTIV 041520.xlsx Francis – the following emails were missing from the list that went out, please see 8 emails listed below Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone. Disbrow, Gary (OS/ASPR/BARDA) < (b)(6)Kim, Elizabeth < (b) (6) Marston, Hilary (NIH/NIAID) [E] (b)(6)Paul, Steve < (b) (6) Payne, David < (b) (6) Plump, Andy (b)(6)Santos, Nancy (b) (6) Shen, Yuan Li (FDA/CDER) (b) (6) Thanks, Ashley From: Collins, Francis (NIH/OD) [E] < (b)(6)Sent: Wednesday, April 15, 2020 11:39 AM To: Melencio, Cheryl (FNIH) [T] < Parker, Ashley (NIH/OD) [E] < (b)(6)(b) (6) Subject: RE. List -- just copy and paste in bcc. lists of April 3 plus working groups I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one? From: Melencio, Cheryl (FNIH) [T] < (b) (6) g> Sent: Wednesday, April 15, 2020 11:19 AM To: Parker, Ashley (NIH/OD) [E] < Collins, Francis (NIH/OD) [E] < (b) (6) (b)(6)Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups Austin, Christopher (NIH/NCATS) [E] < Bright, Rick < Collins, Francis (b) (6) (b) (6) (NIH/OD) [E] >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Corey, Larry (b) (6) (b)(6)Dolsten, Mikael >; Erbelding, Emily (NIH/NIAID) [E] (b) (6) r; Fauci, Anthony (NIH/NIAID) [E] (b) (6) ; Frankowski, David Hudson, Thomas ; James, Stephanie (FNIH) (b) (6) (b) (6) >; Klock, Kevin (FNIH) [T] < (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6) (b) (6) Marks, Peter (FDA/CBER) Marston, Hilary (NIH/NIAID) [E] (b) (6) (b) (6) Mascola, John >; Meeker, David Menetski, Joseph (FNIH) [T] (b) (6) (b) (6) (b) (6) Pangalos, Mene < Pao, William < (b)(6)(b) (6) Paul, Steve < ; Perlmutter, Roger Plump, Andy (b) (6) (b) (6) >; Rasi, Guido >; Reed, John >: Rouse. (b) (6) (b)(6)(b)(6)

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Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky, Daniel
        (b) (6) Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
                                             (b) (6)
     (b) (6)
               >: Tabak, Lawrence (NIH/OD) [E]
                                                         Tsai. John
                 Vessey, Rupert (b) (6) >; Virgin, Skip (b) (6) Wholley, David
(b)
(FNIH) [T] (b) (6) >; Woodcock, Janet (FDA/CDER) < (b) (6) >; Young, John
< (b) (6) Adam, Stacey (FNIH) [T] (b) (6) >; Bascles, Lionel
                  Cohen, Myron < (b) (6) >; Corey, Larry · (b) (6)
        (b) (6)
Desrosiers , Betsy
                   (b) (6)
                                     Dickens, Jim (NiH/NCATS) [C] (b) (6)
                                                                            >;
Doroshow, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E] <
                                                                 (b) (6)
                                                                            Heaton,
Penny < (b) (6)
                     King, James (b) (6) >; Kurılla, Mike < (b) (6) >; Nayak,
Seema (NIH/NIAID) [E] (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Payton, Manzine
(b) (6) >; Resnansky, Laura (b) (6) >; Srinivasan, Badhri
    Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6)
Sam (NIH/NCATS) [E] < (b) (6) >; Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6)
                                                                  (b) (6)
                                                                           Bozzette,
                                                                            '>;
                              >; De Claro, R. Angelo (FDA/CDER) (b) (6)
Butterton, Joan
                   (b) (6)
Draghia-Akli, Ruxandra <
                      (b) (6) Eisner, Mark < (b) (6) Gottesdiener, Keith
 (b) (6)
(b) (6)
                     i>; Hughes, Eric
                                   (b) (6)
                                                  >; Judy Currier
                Kim, Elizabeth (b) (6) ; LaVange, Lisa (b) (6)
                                                                          ; Levy, Elliot
              . Mellors, John < (b) (6) Menon, Sandeep < (b) (6) Parket (b) (6) Patel, Naimish (b) (6) 1>; Peppercorn, Amanda
                                                             (b) (6) Parker,
< (b) (6)
Ashley (NIH/OD) [E]
                >; Poole, Mike < (b) (6) >; Proschan, Michael
         (b) (6)
< (b) (6)
                 ; Read, Sarah < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen,
                 (b) (6) Stein, Peter (FDA/CDER) (b) (6) >; Adams, Peter
Yuan Li (FDA/CDER)
(OS/ASPR/BARDA) (b) (6) >; Alvarez, Rosa < (b) (6) >; Anderson, Annaliesa
                         Baric, Ralph (b) (6) Carter, Kara (b) (6)
 (b) (6)
Colvis, Christine (b) (6) Deming, Damon (FDA/CDER) < (b) (6) Diamond.
Michael (b) (6) >; Duncan, Ken (b) (6)
                                                         >; Fernandes, Prabhavathi
   (b) (6) >; Gatto, Greg (b) (6) Grobler, Jay (b) (6) Hewitt, Ju
(b) (6) >; Jonson, Samantha (NiH/NCATS) [E] (b) (6) >; Lutz, Cat < (b) (6)
                                                                     Hewitt, Judith
Menetski, Joseph (FNIH) [T] < (b) (6) Nestle, Frank
                                                    (b) (6) >; Ottinger, Liz
 (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) Payne, David
< (b) (6)
                   Rappaport, Jay (b) (6) >; Stegmeier, Frank (b) (6)
                (b) (6) Annunziato, Paula (b) (6) Arvin, Ann
Young, John <
               Buchbinder, Susan (b) (6)
(b) (6)
                                                  >; Corey, Larry < (b) (6) >;
              (b) (6) Emini, Emilio <
Davis, Mark <
                                                (b) (6) Hanon, Emmanuel
< (b) (6)
                      Haynes, Barton < (b) (6)
                                                   . Hotez, Peter < (b) (6) Jansen,
Kathrin (b) (6) >; Lanzavecchia, Antonio <
                                                  (b) (6) Lowy, Douglas (NIH/NCI) [E]
                Marks, Peter (FDA/CBER) (b) (6)
                                                     ; Mascola, John (NIH/VRC) [E]
      (b) (6)
                ; Messonnier, Nancy (CDC/DDID/NCIRD/OD)
                                                     (b) (6) ; Offit, Paul
      (b) (6)
            Parker, Ashley (NIH/OD) [E] (b) (6)
                                                      Santos, Nancy (b) (6)
      (b) (6)
Schuitemaker, Hanneke < (b) (6) Tartaglia, Jim <
                                                              Tolman, Brett
      (b) (6) (b) (6) (b) (6)
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Cheryl Melencio

Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 12/10/2020 10:27:33 PM Hild, Sheri (NfH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa); (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email. Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Tomas Cihiar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cbSe933c6ee7a6bc7-punturiena]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Wholley, David (FMH) [T] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa742841Sbb86087d08b628e6f-melencioc]; Colvis, Christ ne (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams[4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user706e5647]; Kim,

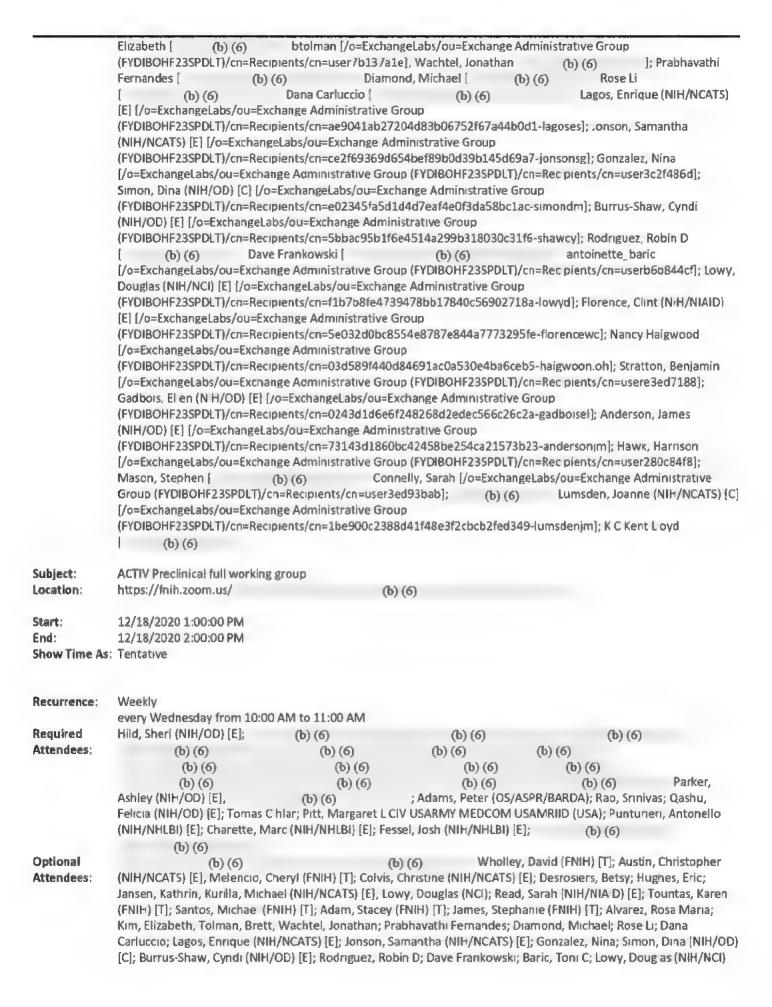
From:

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To:

CC.

APAR0000017792-2516882



[E]; Forence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen, Connelly, Sarah; (b) (6) .com; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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US (Houston)

Meet ng ID: (b) (6) Passcode: (b) (6)

Find your local number: https://fnih.zoom.us/ (b) (6)

From:

Brodd, Lauren (NiH/OD) [F] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]

Sent:

3/4/2021 7:05:58 PM

To:

Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras)

Subject:

RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Thanks for the update

From: Parker, Ashley (NtH/OD) [E] < (b) (6)

Sent: Thursday, March 4, 2021 1:38 PM

To: Brodd, Lauren (NIH/OD) [E] <

(b) (6)

Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

For updating our rosters, please see below.

Thanks, Ashley

From: Wholley, David (FNIH) [T] < (b) (6)

Sent: Thursday, March 4, 2021 1:08 PM

To: Myles, Renate (NIH/OD) [E]

>; Meltzer, Abbey (FNIH) [T] (b) (6)

(b) (6) >; Thompson,

Katherine (FNIH) [T]

(b) (6)

Cc: Freire, Maria (FNIH) [T] (b) (6) ; Santos, Michael (FNIH) [T] (FNIH) (T) < (b) (6) Meltzer, Abbey (FNIH) [T]

(b) (6)

>; Melencio, Cheryl (b) (6)

(b)(6)

Parker, Ashley (NIH/OD) [E] <

>; Collins, Francis (NIH/OD) [E] ; Gonzalez, Nina

(b) (6)

Appell, Evan

(b) (6)

Subject: FW: Notes from Wednesday's ACTIV Leadership Team Meeting

Can we please add Gary Dubin to the Vaccine WG rosters on the NIH and FNIH websites, and substitute Rajeev Venkayya for Andy Plump as the rep for Takeda to the ACTIV Leadership Team?

Francis, I am assuming this means Andy is also asking that Rajeev replace him on the Executive Committee. He's got a good background for PPPs—worked for four years on the WH biodefense team (wherefrom he knows Tony Fauci), is Andy's counterpart at Takeda as global head of their vaccines business, directed vaccines delivery at BMGF, and serves on the boards of SEPI and IAVI. I found him engaging and impressive, and am guessing Mike did too.

Thanks, David

From: Burke, Leslie < On Behalf Of Venkayya, Rajeev (b)(6)

Sent: Thursday, March 4, 2021 12:03 PM

(b)(6)To: Santos, Michaei (FNIH) [T]

Cc: Wholley, David (FNIH) [T] < ; Melencio, Cheryl (FNIH) [T] >; Venkayya, (b) (6)

Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Mike,

I'm following up on Rajeev's behalf to let you know he would like to recommend his colleague **Gary Dubin, MD** for the Vaccines WG. Gary is the Head of our Global Medical Office, and leads the Takeda Vaccine Business Medical Affairs and Policy team. (b)(6)is his Executive Assistant. Gary will look forward to connecting! Please don't hesitate to reach out with any questions. Many thanks, Leslie Burke EA to Rajeev Venkayya, MD, President, Global Vaccine Business Unit Vaccine Business Unit Takeda Pharmaceutical Company Limited Mall to: 40 Landsdowne Street, Cambridge, MA 02139, USA Office location: 75 Sidney Street, Cambridge, MA 02139, USA mobile: (b) (6) email: | www.takedavaccines.com (b) (6) From: Santos, Michael (FNIH) [T] (b) (6) Sent: Monday, March 1, 2021 12:04 PM To: Venkayya, Rajeev (b) (6) Cc: Wholley, David (FNIH) [T] Melencio, Cheryl (FNIH) [T] < Burke, Leslie (b)(6)(b) (6) (b) (6) Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting Be advised that this email came from outside Takeda / お知らせ . 社外から送信されたメールです Hi Rajeev, It was great meeting and chatting. Your experience and perspectives are a great addition to the group. As we discussed, attached are notes from the last few Vaccines WG meetings. The meetings are not under NDA, but our principle is that information shared during the meetings should only be used to advanced the shared objective of supporting COVID-19 vaccine development. So please feel free to share with the relevant people in your team, but not publicly. If anyone is interested in joining the Vaccines Working Group, please let us know and we'll be happy to add them. Best regards, Mike Michael Santos, PhD Associate Vice President, Science | Foundation for the National Institutes of Health From: Venkayya, Rajeev (b) (6)

; Melencio, Cheryl (FNIH) [T]

Sent: Friday, February 19, 2021 11:21 PM

(b) (6)

(b) (6)

To: Santos, Michae (FNIH) [T] <

Cc: Wholley, David (FNIH) [T]

Burke, Leslie

(b) (6)

(b) (6) >

Subject: Re: Notes from Wednesday's ACTIV Leadership Team Meeting

Dear Michael.

Thanks for the kind introduction and background. I know FNIH well and am looking forward to working with you. And yes, I'm sure we have many colleagues in common from BMGF!

An onboarding call would be helpful if it's not too much trouble. I'll ask Leslie to work with you to set that up I look forward to that, and to meeting the ACTIV group!

Regards,

Rajeev

From: Santos, Michael (FNIH) [T] (b) (6)

Sent: Friday, February 19, 2021 4:59:22 PM

To: Venkayya, Rajeev (b) (6)

Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6)

Subject: RE: Notes from Wednesday's ACTIV Leadership Team Meeting

Be advised that this email came from outside Takeda / お知らせ:社外から送信されたメールです

Dear Rajeev,

We heard from Andy Plump and Francis Collins that you are joining ACTIV. We're delighted to have you on the team.

The Foundation for the NIH manages ACTIV; David Wholley leads our work overall, I manage the Vaccines Working Group, and my counterparts manage the other Working Groups. If you are interested, we would be happy to have a call to provide context on ACTIV and the Vaccines Working Group and answer any questions that you have.

On a personal note, I was at BMGF for almost 6 years on the Discovery and HIV teams before I joined FNIH in late 2019. Although we missed overlapping there, I'm sure we know many people in common and I hope that we'll have the opportunity to connect sometime.

Best regards,

Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Melencio, Cheryl (FNIH) [T] (b) (6) > On Behalf Of Wholley, David (FNIH) [T]

Sent: Friday, February 19, 2021 4:07 PM

To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bancel, Stephane
(b) (6) >; Carter, Kara (b) (6) . Cavaleri, Marco

(b) (6) >; Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E] (b) (6) Corey, Larry < (b) (6) >; Culp, Michelle (NIH/OD) [E] (b) (6)

Victoria Davey (b) (6) , Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >; Dolsten, Mikael (b) (6) >, Embry, Alan (NIH/NIAID) [E] (b) (6) Erbelding, Emily (NIH/NIAID) [E]

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Erck, Stan (b) (6) >; Fauci, Anthony (NIH/NIAID) [E] <
       (b) (6)
Freire, Maria (FNIH) [T] (b) (6) >; Gadbois, Ellen (NIH/OD) [E] (b) (6) >; Gibbons, Gary
                            >, Hudson, Thomas (b) (6)
(NIH/NHLBI) [E] (b) (б)
                                                               >: James, Stephanie (FNIH) [T]
            >; Johnson, Robert (OS/ASPR/BARDA) (b) (6)
    (b) (6)
                                                       >; Kramer, Lynn
       (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Lepore, John (b) (6)
Marks, Peter (FDA/CBER) (b) (6) >; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker,
David
            (b) (6)
                        . Menetski, Joseph (FNIH) [T] (b) (6) >; Messonnier, Nancy
                   (b) (6) ; Pandya, Hitesh <
(CDC/DDID/NCIRD/OD)
                                                                   Pangalos, Mene
                                                     (b) (6)
                  >; Pao, William
                                                      >; Parker, Ashley (NIH/OD) [E]
          (b) (6)
                                          (b) (6)
                 >; Paul, Steve (b) (6)
                                           >; Perlmutter, Roger
< (b) (6)
                                                                   (b) (6)
Plenge, Robert < (b) (6) Reed, John (b) (6) Reese, David
                                                                     (b) (6)
Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] (b) (6) >; Skovronsky, Daniel
                     >: Stein, Peter (FDA/CDER) <
                                                         > Stoffels, Paul
        (b) (6)
                                             (b) (6)
               >; Tabak, Lawrence (NIH/OD) [E]
                                               (b) (6) ; Talley, Michael
     (b) (6)
                   >; Tsai, John (b) (6)
                                             . Venkaγya, Rajeev < (b) (6)
       (b) (6)
Vessey, Rupert
                                          (b) (6) Wholley, David (FNIH) [T] (b) (6)
                 (b) (6) >; Virgin, Skip
                          (b) (6)
                                          . Young, John (b) (6)
Woodcock, Janet (FDA/OC) <
                                                                          >; Colvis,
Christine (NIH/NCATS) [E]
                                     . Desrosiers, Betsy
                                                            (b) (6)
                                                                             >: Eric
                          (b) (6)
                         >; Jansen, Kathrin < (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
Hughes
             (b) (6)
                   Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) >;
(b) (6)
                 (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Margaret Anderson
Young, John
                    >; Appell, Evan (b) (6) Chen, Helen
                                                                  (b) (6) >;
       (b) (6)
                   (b) (6) Dally, Nicolle (b) (6) Gonzalez, Nina
Connelly, Sarah
                     Hawk, Harrison < (b) (6)
                                                 Mendelson, Jesse <
< (b) (6)
                                                                         (b) (6)
Menetski, Joseph (FNIH) [T] (b) (6) >; Nasr, Hana (b) (6) >; Santos, M chael (FNIH) [T]
     (b) (6) Sorosa, Alex (b) (6) Stratton, Benjamin (b) (6) >; Tolman,
           (b) (6)
                      , Wachtel, Jonathan (b) ; Wholley, David (FNIH) [Т]
Brett
                Plump, Andrew (b) (6)
                                                 >
      (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) >;
                  (b) (6) Castillejos, Carlos < (b) (6)
Carluccio, Dana <
                                                                   ; FNIH Central Account
                   >; Lumsden, Joanne (NIH/NCATS) [C] (b) (6)
       (b) (6)
                                                                    Hallett, Adrienne
           (b) (6) >; Meltzer, Abbey (FNIH) [T] <a (b) (6)
(NIH/OD) [E]
                                                               Myles, Renate (NIH/OD) [E]
     ரு கு >: Wolinetz, Carrie (NIH/OD) [E]
                                         (b) (6)
Subject: Notes from Wednesday's ACTIV Leadership Team Meeting
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Dear Leadership Team members and meeting attendees:

Please see the notes from our teleconference this past Wednesday, February 17. Please let me know of any additional comments, questions, or suggestions regarding these notes.

Thank you again for all your support of and contributions to ACTIV.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
(nth.org
11400 Rockville Pike Suite 600 North Berhesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent:

7/29/2020 10:19:49 PM

To:

Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject:

FW: Materials for July 29 ACTIV Executive Committee Teleconference

Attachments: 2020-07-01 ACTIV Leadership Team Meeting Summary FINAL.docx; 2020-07-

15 Executive Committee Meeting_Summary vFinal docx; 7.29 ACTIV Leadership Team Meeting 20200729

vFinal.pptx

FYI-LEADERSHIP TEAM SLIDES ATTACHED 7/29

Trottin in cicitato, che	ryl (FNIH) [T] < (b) (6)	On Behalf Of Wholley, David (FNIH) [T]
	8, 2020 10:53 PM	
To: Austin, Christoph	er (NIH/NCATS) [E] < (b) (c	6) Bancel, Stephane
< (b) (6	Carter, Kara <	(b) (6) Cavaleri, Marco (b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6)	Cihlar, Tomas <	(b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6)	Corey, Larry < (b) (6)	Culp, Michelle (NIH/OĐ) [E] < (b) (6)
Disbrow, Gary (OS/AS	SPR/BARDA) < (b) (6)	Dolsten, Mikael < (b) (6) Erbelding,
Emily (NIH/NIAID) [E]	< (b) (6) Erck	s, Stan < (b) (6) Fauci, Anthony (NIH/NIAID) [E]
< (b) (6)	Freire, Maria (FNIH) [T] <	(b) (6) Gadbois, Ellen (NIH/OD) [E]
< (b) (6)	Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) Hudson, Thomas IH) [T] < (b) (6) Johnson, Robert (OS/ASPR/BARDA)
< (b) (6)	James, Stephanie (FN	IH) [T] < (b) (6) Johnson, Robert (OS/ASPR/BARDA)
< (b) (6)	Kramer, Lynn <	(b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6)
Lepore, John <	(b) (6) Marks, Peter (FDA/CBER) < (b) (6) Marston, Hilary
(NIH/NIAID) [E] <	(b) (6) Mascola, Jo	ohn (NIH/VRC) [E] < (b) (6) Meeker, David T] < (b) (6) Messonnier, Nancy
< (b) (6)	Menetski, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy
(CDC/DDID/NCIRD/O	D) < (b) (6) Pandya, Hit	tesh < (b) (6) Pangalos, Mene
< (b) (6) Pao, William <	(b) (6) Parker, Ashley (NIH/OD) [E] Perlmutter, Roger < (b) (6)
Plenge, Robert <	(b) (6) Plump, Andy	< (b) (6) Rachel Ramoni
< (b) (6)	Rasi, Guido < (b)	(6) Reed, John < (b) (6) Reese, David
< (b) (6)	Rouse, Doris < (b) (6)	Santos, Michael (FNIH) [T] < (b) (6) Skovronsky,
Daniel <	b) (6) Stoin Botor (EF	A/CDEP) / (b) (c) Stoffele Poul
Daniel .	b) (b) Stelli, reter (rt	DA/CDER) < (b) (6) Stoffels, Paul
< (b) (6)	Tabak, Lawrence (NIH/OD) [E]	< (b) (6) Talley, Michael
< (b) (6) < (b) (6)	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b)	 (b) (6) Talley, Michael (6) Vessey, Rupert < (b) (6) Virgin, Skip
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 (b) (6) (c) Bianchi, D ana (Ni Roger (NIH/FIC) [E] 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (to Young, John < to Desrosiers, Betsy < to Jansen, Kathrin < to Lowy, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) Hodes, Rich	(b) (6) Talley, Michael (6) Vessey, Rupert (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [F] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Byrnes, Noni (NIH/CSR) [E] (b) (6) Glass, Mard (NIH/NIA) [E] Arard (NIH/NIA) [E] (b) (6) Koob, George
 (b) (6) (c: Bianchi, D ana (Ni Roger (NIH/FIC) [E] < (NIH/NIAAA) [E] 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (to Young, John < to Desrosiers, Betsy < to Jansen, Kathrin < to Lowy, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) (b) (6) Hodes, Rich (b) (6) Koroshetz, V	 (b) (6) Talley, Michael (6) Vessey, Rupert < (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [F] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Byrnes, Noni (NIH/CSR) [E] < (b) (6) Glass, nard (NIH/NIA) [E] < (b) (6) Koob, George Walter (NIH/NINDS) [E] < (b) (6) Langevin,
 (b) (6) Young, John Cc: Bianchi, D ana (Ni Roger (NIH/FIC) [E] (NIH/NIAAA) [E] Helene (NIH/NCCIH) 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (to Young, John < to Desrosiers, Betsy < to Jansen, Kathrin < to Lowy, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) (b) (6) Hodes, Rich (b) (6) (b) (6) Koroshetz, V (E] < (b) (6) N	 (b) (6) Talley, Michael (6) Vessey, Rupert < (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [F] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Byrnes, Noni (NIH/CSR) [E] < (b) (6) Glass, hard (NIH/NIA) [E] < (b) (6) Koob, George Walter (NIH/NINDS) [E] < (b) (6) Langevin, forris, Andrea (NIH/CIT) [E] < (b) (6)
 (b) (6) (c: Bianchi, D ana (Ni Roger (NIH/FIC) [E] < (NIH/NIAAA) [E] < Helene (NIH/NCCIH) Stable, Eliseo (NIH/N 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (to Young, John < to Desrosiers, Betsy < to Jansen, Kathrin < to Lowy, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) (b) (6) Hodes, Rich (b) (6) (b) (6) Koroshetz, W [E] < (b) (6) N [MHD] [E] < (b) (6)	 (b) (6) Talley, Michael (6) Vessey, Rupert < (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [F] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Byrnes, Noni (NIH/CSR) [E] < (b) (6) Glass, hard (NIH/NIA) [E] < (b) (6) Koob, George Walter (NIH/NINDS) [E] < (b) (6) Langevin, horris, Andrea (NIH/CIT) [E] < (b) (6) Perez-Rodgers, Griffin (NIH/NIDDK) [E]
 (b) (6) (c: Bianchi, D ana (Ni Roger (NIH/FIC) [E] < (NIH/NIAAA) [E] < Helene (NIH/NCCIH) Stable, Eliseo (NIH/N (b) (6) 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (t Young, John < Desrosiers, Betsy < Jansen, Kathrin < Lowy, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) (b) (6) Hodes, Rich (b) (6) Koroshetz, W [E] < (b) (6) Schwetz, Tara (NIH/OD)	 (b) (6) Talley, Michael (6) Vessey, Rupert < (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [E] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Byrnes, Noni (NIH/CSR) [E] < (b) (6) Glass, nard (NIH/NIA) [E] < (b) (6) Koob, George Walter (NIH/NINDS) [E] < (b) (6) Langevin, forris, Andrea (NIH/CIT) [E] < (b) (6) Perez-Rodgers, Griffin (NIH/NIDDK) [E] (b) (6) Sharpless, Norman (NIH/NCI) [E]
 (b) (6) (c: Bianchi, D ana (Ni Roger (NIH/FIC) [E] < (NIH/NIAAA) [E] < Helene (NIH/NCCIH) Stable, Eliseo (NIH/N (b) (6) (b) (6) 	Tabak, Lawrence (NIH/OD) [E] Tsai, John < (b) holley, David (FNIH) [T] < (to Young, John < to Young, Douglas (NCI) < (b) (6) H/NICHD) [E] < (b) (6) (b) (6) Koroshetz, V [E] < (b) (6) NHD) [E] < (b) (6) Schwetz, Tara (NIH/OD Tucci, Debara (NIH/NID)	(6) Vessey, Rupert (b) (6) Virgin, Skip (b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Colvis, Christine (NIH/NCATS) [F] (b) (6) Eric Hughes (b) (6) Kurilla, Michael (NIH/NCATS) [E] (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) Byrnes, Noni (NIH/CSR) [E] (b) (6) Glass, More (NIH/NIAID) [E] Malter (NIH/NINDS) [E] (b) (6) Langevin, Morris, Andrea (NIH/CIT) [E] (b) (6) Perez-Rodgers, Griffin (NIH/NIDDK) [E] (b) (6) Sharpless, Norman (NIH/NCI) [E] CD) [E] (b) (6) Tumminia, Santa (NIH/NEI) [E]
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(b) (6) Gonzalez, Nina < (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stratton, Ben (b) (6) Tolman, Brett < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) < Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Anderson, James Burklow, John (NIH/OD) [E] < (NIH/OD) [E] < (b) (6) Castillejos, Carlos (b) (6) < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6) **FNIH Central Account** Gadbois, Ellen (NIH/OD) [E] < Freire, Maria (FNIH) [T] < (b) (6) (b) (6) < Wolinetz, Carrie (NIH/OD) [E] < Burklow, John (NIH/OD) [E] (b) (6) (b) (6) < Gorman, Greta (FNIH) [T] < Hallett, Adrienne (NIH/OD) [E] (b) (6) (b) (6) < Meltzer, Abbey (FNIH) [T] < Myles, Renate (NIH/OD) [E] (b) (6) (b) (6) < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Subject: Materials for July 29 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as

well as our last ACTIV EC meeting on July 15.

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Sent: 7/29/2020 10:19:13 PM

Subject: FW: Materials for July 29 ACTIV Executive Committee Teleconference

Attachments: 2020-07-01_ACTIV_Leadership_Team_Meeting_Summary FINAL.docx; 2020-07-

15 Executive Committee Meeting_Summary vFinal.docx; 7.29 ACTIV Leadership Team Meeting 20200729

vFinal.pptx

From: Melencio, Cheryl	(FNIH) [T] < (b) (6)	On Behalf Of Wholley, David (FNIH) [T]
Sent: Tuesday, July 28, 3	2020 10:53 PM	
To: Austin, Christopher	(NIH/NCATS) [E] < (b)) (6) Bancel, Stephane
(h) (6)	Carter Kara <	(b) (6) Cavaleri Marco
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Plenge, Robert <	(b) (6) Plump, And	dy < (b) (6) Rachel Ramoni
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< (b) (6)	Rouse, Doris < (b) (6)	Santos, Michael (FNIH) [T] < (b) (6) Skovronsky,
Daniel < (b)	(6) Stein, Peter ((FDA/CDER) < (b) (6) Stoffels, Paul
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Stable, Eliseo (NIH/NIM		Rodgers, Griffin (NIH/NIDDK) [E]
< (b) (6)	Schwetz, Tara (NIH/	
< (b) (6)	Tucci, Debara (NIH/N	
< (b) (6)	Volkow, Nora (NIH/NIDA	(b) (6) Woychik, Rick (NIH/NIEHS) [E]
< (b) (6)	Adam, Stacey (FNIH) (T) <	(b) (6) Alvarez, Rosa < (b) (6)
Anderson, Margaret <	(b) (6)	Chen, Helen < (b) (6) Elsaid, Olivia
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(NIH/	OD) [E] <	(b) (6)	Burklow, John	(NIH/OD) [E] <	(b) (6)	Castillejos, Carlos
<	(b) (6)	Culp, Michelle (NIH/OD) [E] <	(b) (6)	FNIH Central	Account
<	(b) (6)	Freire, Ma	aria (FNIH) [T] <	(b) (6)	Gadbois, Ellen (N	IIH/OD) [E]
<	(b) (6)	Wolinetz, Cari	rie (NIH/OD) [E] <	(b) (6) Burklow	, John (NIH/OD) [E]
<	(b) (6)	Gorman, Greta	(FNIH) [T] <	(b) (6)	Hallett, Adrienne	NIH/OD) [E]
<	(b) (6)	Meltzer, A	bbey (FNIH) [T] <	(b) (6)	Myles, Renate	(NIH/OD) [E]
<	(b) (6)	Melencio, Cher	yl (FNIH) [T] <	(b) (6)		

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC1 on behalf of Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] 11/18/2020 9:49:33 PM Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane Carter, Kara Cavaleri, Marco (b) (6) (b) (6) Cihlar, Tomas [Collins, Francis (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingei]; Erck, Stan. Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel); Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2eS27dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, .ohn (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola}; Meeker, David]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp], Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh Pangalos, Mene [Pao, William (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] (/o=ExchangeLabs/ou=Exchange Administrative Group) (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras), Paul, Steve Perimutter, Roger [Plenge, Robert (b) (6) (b) (6) (b) (6) Plump, Andy [(b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido Reed, John (b) (6) Reese, David [Rouse, Doris Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Skovronsky, Daniel Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael Tsai, John [Vessey, Rupert []; Virgin, (b) (6) (b) (6)

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Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group]
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana
                                    Castillejos, Carlos [
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmi]; Me tzer, Abbey (FNIH)
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CC:

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]

Subject: ACTIV Leadership Team Meeting November 19, 2020

Attachments: 11.19 ACTIV Leadership Team Meeting 20201118_vf.pdf; 11.19 ACTIV Leadership Team Meeting

20201118 Appendix.pdf; 2020-10-21 ACTIV Leadership Team Meeting Summary-FINAL.docx; 2020-11-

04 Executive Committee Meeting_Summary vF.pdf

Dear AMP Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow**, **Thursday**, **November 19 12:00 PM - 1:00 PM Eastern U.S. Time**. The minutes from the October 21 Leadership Team call as well as the minutes from the November 4 Executive Committee call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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Find your local number: https://fnlh.zoom.us/ (b) (6)

United Kingdom

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as un organization that exceeds industry standards.

Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 4/14/2020 10:48:29 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email; Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas /US Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Qashu, Fel cia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Tomas Cihlar Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Desros ers, Betsy Hughes, Enc [(b) (6) (b) (6) Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria Kim, Elizabeth Tolman, Brett [Wachtel, (b) (6) Jonathan Prabhavathi Fernandes [Diamond, Michael (b) (6) (b) (6)

Dana Carluccio

Rose Li

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From:

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Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski Lowy, Douglas (NIH/NCI) [E] (b) (6) (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NiH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Louise Pitt Nancy Haigwood [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa] Subject: ACTIV Preclinical working group (Friday meeting) Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment https://fnih.zoom.us/ Location: (b)(6)Start: 4/24/2020 3:00:00 PM End: 4/24/2020 4:00:00 PM Show Time As: Busy Recurrence: Weekly every Fr day from 11:00 AM to 12:00 PM Required (b) (6) (b) (6) (b) (6) (b) (6) Attendees: (b) (6) (b)(6)(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b)(6)(b) (6) (b)(6)Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas /US; Anderson, James (NIH/OD) [E]; Qashu, Felicia (NIH/OD) [E]; Tomas Cinlar; Punturieri, Antonello (NIH/NHLBI) [E], Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E] Optional Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine Attendees: (NIH/NCATS) [E], Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michae (NIH/NCATS) [E]; Lowy, Doug as (NCI), Read, Sarah (NIH/NIAID) [E], Tountas, Karen (FNIH) [T], Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth, Tolman, Brett, Wachtei, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio, Lagos, Enrique (NIH/NCATS) [6]; Jonson, Samantha (NIH/NCATS) [E], Gonzalez, N na, Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D; Dave Frankowski, Lowy, Douglas (NIH/NCI) [E], Florence, Clint (NIH/NIAID) [E], Louise Pitt (Nancy Haigwood; Hild, Sheri (NIH/OD) [E] Holding time Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnsh.zoom.us/ (b) (6) Meeting ID: (b) (6)

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From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]

Sent:

9/9/2020 5:37:26 PM

To:

Brodd, Lauren (NiH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm)

Subject:

FW: ACTIV Therapeutics-Clinical Working Group Meeting

Attachments: DRAFT ACTIV Checkerboard 9.4.20.pdf

This might help. Or it might be too much info!

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----Original Message---
From: Chen, Helen Q. <
                                   (b)(6)
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T]
                                       (b) (6)
                                                     Bozzette, Sam (NIH/NCATS) [E] <
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Butterton, Joan <
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Draghia-Akli, Ruxandra <
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Levy, Elliot <
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                                                                                                            Read, Sarah
                                    Stein, Peter (FDA/CDER) <
Buchman, Tim (OS/ASPR/BARDA) (CTR) <
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Rosenberg, Yves (NIH/NHLBI) [E] <
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Jacqueline Kirchner
                         Brown, Jeremy (NIH/NINDS)
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(NIH/NHLBI) [E] <
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Hilary (NIH/NIAID) (E <
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(NIH/NHLBI) [E] <
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Allan (NIH/NHLBI) IEI <
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                                  Hone, David M (Dave) CIV DTRA 19 (USA) «
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Reisler. Ronald B CTR USARMY DOD JPEO CBRND (USA) <
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                                                                                               Freire, Maria (FNIH)
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                           Elsaid, Olivia <
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                                                                        Appell, Evan <
[T] <
                                                                                                 (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting
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Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards, Stacey, Mike, and Helen

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----Original Appointment----
From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Elsner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - O449 - MITLL; rwmalonemd@gmail.com; Sizemore, Christine (NIH/FIC) [E]
 ----Original Appointment-----
(NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA);
Petrovick, Martha - 0449 - MITLL; rwmalonemd@gmail.com; Sizemore, Christine (NIH/FIC) [E]

Cc Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS)

[E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio,
Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James,
Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana

Carluccio: Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;

(b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI)

[E,; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NHAID) [E]; Chen, Helen Q.; Wung, Peter /US;
Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski,
Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO
CBRND (USA): Freire, Maria (FNIH) [T]: Elsaid, Olivia
 CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
 Subject: ACTIV Therapeutics-Clinical Working Group Meeting
when: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada). where: https://fnih.zoom.us/ (b)(6)
 Stacey Adam is inviting you to a scheduled Zoom meeting.
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 Password: (b)(6)
Find your local number: https://fnih.zoom.us/u/admJcy5VBq This message (including any attachments)
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From; (b)

(b) (6) [(b) (6)

Sent:

5/13/2020 10:46:47 AM

To:

Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject:

Fwd: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; ATT00001.htm; Proposal for ACTIV leaderhsip-vF 051220.pdf;

ATT00002.htm

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" (b) (6)

Date: May 12, 2020 at 9:57:04 PM EDT

To: "Collins, Francis (NIH/OD) [E]" (b) (6) . "Dolsten, Mikael"

(b) (6) . "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) "Gibbons, Gary (NIH/NHLB) [E]" (b) (6) >, "Pao, William" < (b) (6) . "Stoffels, Paul

[JJCUS]" < (b) (6) , "Woodcock, Janet (FDA/CDER)" < (b) (6)

"Colvis, Christine (NIH/NCATS) [E]" (b) (6) >, "Desrosiers, Betsy"

(b) (6) "Hughes, Eric" (b) (6) "Jansen, Kathrin" (b) (6) , "Kurilla, Michael (NIH/NCATS) [E]" (b) (6) >, "Lowy, Douglas (NIH/NCI) [E]" (b) (6) "Read, Sarah (NIH/NIAID) [E]" (b) (6)

"Young, John" (b) (6) >, "Menetski, Joseph (FNIH) [T]" (b) (6) ,
"Adam, Stacey (FNIH) [T]" (b) (6) , "Tountas, Karen (FNIH) [T]" (b) (6)

"Santos, M chael (FNIH) [T]" (b) (6) , "Freire, Maria (FNIH) [T]" (b) (6)
"Tabak, Lawrence (NIH/OD) [E]" (b) (6) , "Lane, Cliff (NIH/NIAID) [E]"

(b) (6) , "Parker, Ashley (NIH/OD) [E]" (b) (6) . "Anderson, James (NIH/OD) [E]" < (b) (6) "Austin, Christopher (NIH/NCATS) [E]"

(b) (6) >, "Wolf-Rodda, Julie (FNIH) [T]" (b) (6) >, "Gonzalez, Nina" (b) (6)

Cc: "Melencio, Cheryl (FNIH) [T]" (b) (6) >, "Wood, Gretchen (NIH/OD) [E]" < (b) (6)

Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Whofley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

infr.org

11400 Rockville Pike State 600 North Bethesda, MD 20852



To:

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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2/4/c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] (/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E]
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Jacqueline Kirchner
                                         Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
                 (b) (6)
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philiips, L Revell CIV
DTRA RD (USA)
                                      Petrovick, Martha - 0449 - MITLL
                       (b) (6)
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                         Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
         (b) (6)
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                     Wung, Peter K [
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Embry, Alan (NIH/NIAID) [E]
                                                  Lerner, Andrea (NIH/NIAID) [E] [
                                   (b) (6)
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Lumsden, Joanne (NIH/NCATS) [C] [
                                         (b)(6)
                                                        ]; Sorosa, Alex David (
                                                                                                    Walker,
                                                                                     (b) (6)
Paula (NIH/NINDS) [E] [
                                             Kındzelski, Andrei (NIH/NHL8I) [E] [
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Shipp, Allan (NIH/NHLBI) [E] [allan.
                                                Groesch, Mary (NIH/NHLBI) [E] [
                                                                                                   ), Hoots,
                                    (b) (6)
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W. Keith (NIH/NHLBI) [E] [
                              (b) (6)
                                          .gov]; Chen, Helen Q. [
                                                                                       Marston, Hilary
(NIH/NIAID) [E] [
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                                       Rubin, Daniel B. (FDA/CDER) [
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                                                                                             Patterson, Amy
(NIH/NHLBI) [E] [
                                        Qashu, Felicia (NIH/OD) [E] [
                                                                                       ]; Menetski, Joseph
                        (b)(6)
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                                                                             Lowy, Douglas (NCI)
(ENIH) [T]
                              Melencio, Cheryl (FNIH) [T] [
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                Colvis, Christine (NIH/NCATS) [E] [
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                           Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group
           (b) (6)
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                                                               Butcher, Tina [
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                                                (b) (6)
Demarcus [
                                    Macone, Erin [
                                                                      Melencio, Cheryl (FNIH) [T]
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                                     Rose Li Central Account [
                                                                                        Lucas Smalldon
               (b) (6)
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                                                                  Mollica, Linda /US
                (b) (6)
                           Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHFZ3SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) [
                                              Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
                             (b) (6)
                             Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex
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CC:

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[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a633636466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne

(NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenim]; Lerner, Andrea

(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53254f4fb04e4bcbabe37940b4b1887-fennellyam]; Embry, A.an (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]

Attachments: ACTIV_TX-Clinical WG Meeting_20210225_v1.pdf

Start: 2/25/2021 6:00:00 PM End: 2/25/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Levy, Ell ot; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER), Draghia-Akli, Ruxandra, Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth, LaVange Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [F]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLB) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (Brown, Jeremy (b) (6) (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine

(NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. See you in a few minutes.

Thanks, Stacey

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To:

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 Start:
 7/1/2020 2:00:00 PM

 End:
 7/1/2020 3:00:00 PM

Recurrence: (none)

Connelly, Sarah [(b) (6) 12/1/2020 10:12:01 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai], Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea}; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp); (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; (b) (6) Diamond, Michael [Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Desros ers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes), Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla}; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBQHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

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Simon, Dina (N	IIH/OD) [C] [/	o=ExchangeLabs	/ou=Exchange A	dministrative G	roup	
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Mason, Stephe	n	(b) (6)		(b) (6)	(b)	(6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
		oe Menetski
Preclinical WG Strategic Objectives - Updates	20 mms	John Young
		Christine Colvis
		ne Menetski
Discuss Viral Mutation and Prediction of Escape	20 mins	John Young
		Christine Colvis
Discuss Subgroup updates		John Young
Preclinical prioritization		Nancy Heigwood
↑ In who strategy	10 mins	Cat Lutz
to Freid Guides	TO Miles	Isis Kanevsky
o Viral Stocks		Clint Florence
Data portal implementation		Sam Jonson
		Nancy Haigwood
Discuss Small Animal Models and NHP Field Guides	10 mins	Cat Lutz
		Isis Kanevsky

Looking forward to talking to everyone tomorrow!

All the best, Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP ----Original Appointment----From: Menetski, Joseph (FNIH) [T] < (b) (6) Sent: Tuesday, April 14, 2020 6:43 PM To: Menetski, Joseph (FNIH) (T); Hild, Sheri (NIH/OD) (E); (b) (6) (b) (6) (b) (6) (b) (6) (b)(6)(b) Baric, Ralph; Ottinger, Elizabeth (NIH/NCATS (b) (6) (b) (6) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); Parker, Ashley (NIH/OD) [E]; Collins, Francis (b) (6) , Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas, Qashu, Felicia (NIH/OD) (NIH/OD) [E]; (b) (6) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kım, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [F]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E], Hawk, Harrison, Diamond, Michael, Mason, Stephen, ; Connelly, Sarah (b) (6) Subject: ACTIV Preclinical full working group When: Wednesday, November 11, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada). Where: https://fnih.zoom. (b) (6) Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom.us (b) (6) Meeting ID: (b) (6) Passcode: (b) (6) One tap mobile (b)(6)US (Germantown) US (Chicago) Dial by your location (b) (6) US (Germantown) US (Chicago) US (New York) JS (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: (b) (6) Passcode: (b) (6) Find your local number: https://fnih.zoom.us (b) (6)

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Mellors, John W [(b) (6) 10/29/2020 5:29:50 PM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [Eisner, Mark (b) (6) Gottesd ener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa Levy, Elliot [(b) (6) (b) (6) (b) (6) Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish Peppercorn, Amanda [Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Carl . Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw); Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwainr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-ibeigel]; Phillips, L Revell CIV DTRA RD (USA) [Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) (b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Kurilla, Michael (NIH/NCATS) [E] Jansen, Kathrin [(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurifla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary [Butcher, Tina (b) (6) (b) (6) Melencio, Cheryl (FNIH) [T] Demarcus [(b) (6) Macone, Erin [(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan btolman |/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e); Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Dana Carluccio Rose Li Central Account [(b) (6) Margaret Anderson (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smalldon Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188); (b) (6) Mollica, Linda /US Qashu, Felic a (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a5S3f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa], Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI8OHF23SPDLT)/cn=Rec pients/cn=user34aa917e]; Wung, Peter /US [Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk), Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Eisaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF235PDLT)/cn=Rec pients/cn=userf0efa7bd); Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1); Bethany Stokes asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]

Subject:

CC:

RE: ACTIV Therapeutics-Clinical Working Group Meeting

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----Original Appointment----
From: Adam, Stacey (FNIH) [T] [mailto
Sent: Wednesday, June 17, 2020 8:47 AM
                                                                                  (b) (6)
To: Adam, Stacey (FNIH) [T]; Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton,
Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER);
Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E];
Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Dacqueline Kirchner; Beigel. John (NIH) [E]; Phillips, L Revell CIV DTRA RD
(USA); Petrovick, Martha - 0449 - MITLL;
                                                                                             (b)(6)
Cc: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Janes, Stephanie (FNIH) [T]; Wachtel, Jonathia, Tolman, Brett; Alvarez, Rosa: Dana Carluccio: Rose
Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b)(6)
Mollica, Linda /LS; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B.
(FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [F]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria
(FNIH) [T]; Elsaid, Olivia; walker, Paula (NIH/NINDS) [E]: Bethany Stokes; asorosa
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, October 29, 2020 1:00 PM-2:00 PM (JTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us (b)(6)
Dear ACTIV TX-Clinical WG,
Please find attached the slides for today's meeting in 20 minutes.
Thanks,
Stacev
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Alvarez, Rosa Maria [(b) (6) 8/10/2020 3:01:56 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NiH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6). (b)(6)Baric, Ralph [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea}; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Dem ng, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp); (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Desros ers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth Tolman, Brett [Wachtel, Jonathan []; (b) (6) (b) (6) (b) (6) Prabhavathi Fernandes [

Diamond, Michael [

(b) (6)

From:

Sent:

To:

CC:

Rose Li

Lagos, Enrique (NIH/NCATS) (b) (6) Dana Carluccio (b) (6) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI8OHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski [(b) (6) (b) (6) Baric, Toni C Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd); Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-fiorencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI8OHF23SPDLT)/cn=Rec pients/cn=usere3ed7188]; Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonim] Subject: RE: ACTIV Preclin cal full working group Attachments: 2020-08-05_Prec inical_WG_Summary_RLA_vF docx Hi all, Hope you had a good weekend. Please see attached for the notes from our last WG meeting on 8/5. Please let us know if you suggest any modifications or have any questions. Best regards, Rosa Rosa M. Álvarez Deloitte Consulting LLP (b) (6) Mobile: www.deloitte.com ----Original Appointment----From: Menetski, Joseph (FNIH) [T] < (b) (6) Sent: Tuesday, April 14, 2020 6:44 PM To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b)(6)(b) (6) (b) (6) (b) (6) Ottinger, Elizabeth (NIH/NCATS Baric, Ralph; (b) (6) (b) (6) (b) (6) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); Parker, Ashley (NIH/OD) [E]; Collins, Francis (b) (6) (b)(6)(b) (6) (NIH/OD) [E]; Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) (b)(6)[E]; Tomas Cihlar; Pitt, Margaret I. CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NiH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/N AID) [E], Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, August 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: https://fnih.zoom (b) (6)

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Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 6/11/2020 7:38:52 PM Hild, Sheri (NfH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa); (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email; Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NiH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm], Tomas Cihiar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, .osh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesselip] Diamond, Michael [Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd); Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa742841Sbb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Enc [Jansen, Kathrin (b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria Kim, Elizabeth Tolman, Brett [Wachtel, (b) (6) (b) (6) (b) (6)

Prabhavathi Fernandes [

From:

Sent:

To:

CC:

Jonathan

(b) (6)

Rose Li

(b) (6)

Lagos, Enrique (NIH/NCATS) Dana Carluccio | (b) (6) (b) (6) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski [(b) (6) (b) (6) Baric, Toni C Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b)(6)Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-fiorencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Stratton, Benjamin Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel] **ACTIV Preclinical full working group** https://fnih.zoom.us (b) (6) 7/29/2020 2:00:00 PM 7/29/2020 3:00:00 PM Show Time As: Tentative Recurrence: Weekly every Wednesday from 10:00 AM to 11:00 AM Hild, Sheri (NIH/OD) [E]: (b) (6) (b)(6)(b)(6)(b) (6) .gov; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b)(6), Adams, Peter (OS/ASPR/BARDA), Rao, Sriniyas, Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIIO (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E] Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Enc; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, M chael (FNIH) [T]; Adam, Stacey (FNIH) [T], James, Stephanie (FNIH) [T], Alvarez, Rosa Maria; Kim, El zabeth; Tolman, Brett; Wachtel, Jonathan, Prabhavathi Fernandes; Rose Li; Dana Carluccio, Lagos, Ennque (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E], Gonzalez, N na, Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D; Dave Frankowski, Baric, Toni C, Lowy, Douglas (NIH/NCI) [E], Florence, Clint (NIH/NIAID) [E], Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E] Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom. (b) (6)

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Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject:			group (Tuesday meeti	ng)			
Attachments:	2020-05-20 F	Prec inical WG S	ummary F1.docx				
Dear Preclinic	cal Working gi	roup members	and attendees,				
			meeting attached. T	hank you for a	very interestin	ng meeting ar	nd all of the work
ou continue	to do for the	ACTIV effort.					
Best regards,							
oe and Rosa							
Original A	\ppointment						
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NIH/OD) [E]							
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From:

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Sent:

5/29/2020 10:44:42 PM

To:

Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject:

Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] <

(b) (6)

wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] <

(b)(6)

wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] <

(b) (6)

Sent: Friday, May 29, 2020 1:59 PM

To: Collins, Francis (NIH/OD) [E] <

(b) (6)

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Cc: Adam, Stacey (FNIH) [T] <

Freire, Maria (FNIH) [T] <

(b) (6) Gonzalez,

Nina <

(b) (6)

Parker, Ashley (NIH/OD) [E] <

(b) (6)

Subject: Key messages re: Immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to

highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
 - ACTIV hiVIG (sponsored by NIAID) in progress
 - ACTIV-1 Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2*- Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) - (Phase II/III) - projected launch June
 - ACTIV-3* Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI NINDS "Master" Network)
 (Phase II/III) – projected launch late June
 - ACTIV-5 De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) similar design to the mAb protocols, networks/sites/agents in discussions now projected launch August (if needed, i.e. if agents are not incorporated into mAb protocols)
 * current priority
 - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
 - Pr oritization Process (v 2.0) for ACTIV: (slide 14 from May 20 EC deck)
 - Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
 [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
 - Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
 - ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running companysponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV 1 includes aggressive efficacy and futil ty assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - a Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)

- All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- "ACTIV 4" Protocol for anticoagulants
 - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Whotley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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11400 Rockville Pike Suite 600 North Bechesda, MD 20852

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

From: (b) (6) (b) (6) Sent: 2/13/2021 4:55:41 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholiey, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Barasch, Kimberly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa); (b) (6) (b)(6)(b) (6) (b)(6)(b) (6) (b)(6)(b) (6) (b)(6)(b) (6) (b) (6) **(b)** (6) (b) (6) Subject: Re: [EXTERNAL] a few follow ups Francis Thanks for generously suggesting Monday. I can make myself available also. Gretchen and Ann can explore if we can get our dream team cross NIH/Pfizer together that day Best (b) (6) On Feb 13, 2021, at 11:49 AM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote: Though it's a federal holiday, Monday might also be a possibility -1'd be fine with that. Francis From: Collins, Francis (NIH/OD) [E] Sent: Saturday, February 13, 2021 11:17 AM (b) (6) (b) (6) Lane, Cliff (NIH/NIAID) [E] Cc: Fauci, Anthony (NIH/NIAID) [E] < (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] < (b) (6) (b) (6) Barasch, Kimberly (NIH/NIAID) [E] < (b) (6) Conrad, Patricia

(NIH/NIAID) [E] < (b) (6

Subject: RE: [EXTERNAL] a few follow ups

Hi Mikael,

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6) (b) (6) Sent: Friday, February 12, 2021 2:32 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group , I am pleased also to present the protease drug highlights myself and john together wour CEO Albert Bourla from Pfizer to meet the three of you

Best (b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16,

(b) (6)

wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team. We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you, Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs.

In this time of SARSCov2 viral evolution , they seems like a drug class w great promise .

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs, I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton. Liesa participated in ACT V since the start within therapeutics related work streams.

Look forward to your response

Best (b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E] (b) (6) > wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? (3) I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Whoiley into that conversation soon.

Best, Francis

From: (b) (6)

Sent: Wednesday, February 10, 2021 8:36 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece with antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active wipotential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE

Confidential update

(b) (4)



(b) (6)

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins, Francis (NIH/OD) [F] (b) (6) > wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this — including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am g ad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic — and an advance desperate y needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Franc s

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLTI/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

10/11/2020 2:44:29 PM

To:

CC:

Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Collins, Francis (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161S47a82f2de-clane]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc)

Subject:

RE: Roster of ACTIV Vaccines WG

Mike, thank you very much for handling this. Francis, I trust you have what you need?

From: Santos, Michael (FNIH) [T] <

(b) (6)

Sent: Saturday, October 10, 2020 5:34 PM

To: Collins, Francis (NIH/OD) [E] <

(b) (6)

Cc: Lane, C'iff (NIH/NIAID) [E] < (b) (6)

Wholley, David (FNIH) [T] <

(b) (6)

Freire, Maria

(FNIH) [T] <

(b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

In case you were looking for the opposite of what I sent in my previous email, this is the list of WG members who are also on the Clinical Trials Sub-Group.

Thanks,

Mike

Name	Organization	
Paula Annunziato	Merck	
Larry Corey	Fred Hutch	
Ann Arvin	Stanford	
Beth Bell	UW	
Marco Cavaleri	EMA	
Emilio Emini	Gates	
Gregory M. Glenn	Novavax	
Marion Gruber	CBER/FDA	
Peter Hotez	Baylor and Texas Children's	
Kathrin Jansen	Pfizer	
Doug Lowy	NCI/NIH	
Peter Marks	CBER/FDA	
John Mascola	VRC/NIH	-
Nelson Michael	WRAIR	
Paul Offit	Penn/CHOP	
Tal Zaks	Moderna	

Michael Santos, PhD

Associate Vice President, Science - Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Saturday, October 10, 2020 3:10 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Lane, C iff (NIH/NIAID) [E] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Freire, Maria

(FNIH) [T] (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, no problem. The list below is only the non-WG members of the Sub-Group.

Thanks, Mike

Name	Organization	
Myron Cohen	UNC	
Elizabeth Desrosiers	Merck	
Macaya Douoguih	181	
Peter Dull	Gates	
Emily Erbelding	NIAID/NIH	
Peter Gilbert	SCHARP/UW	
Paul Gillard	GSK	
B II Gruber	Pfizer	
Sanjay Gurunathan	Sanofi	
Holli Hamilton	BARDA	
Ian Hirsch	AZ	
Laurent Humeau	Inovio	
Cneryl Keech	Novavax	
Kenneth Koury	Pfizer	
Michael Kurilla	NCATS/NIH	
Julie Ledgerwood	NIAID/NIH	
Maarten Leyssen	181	
Mary Marovich	NIAID/NIH	
Hilary Marston	NIAID/NIH	
Stacey Martín	CDC	
Jacqueline Miller	Moderna	
Kayvon Modjarrad	WRAIR	
Kathleen Neuzil	Maryland	
Ashley Parker	NIH	
Merlin Robb	Henry Jackson Foundation	
François Roman	GSK	
Jerald Sadoff	181	
Stephanie Schrag	CDC	
Sheri Schully	NIH	

Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna

Michael Santos, PhD

Associate Vice President, Science - Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] (b) (6)

Sent: Saturday, October 10, 2020 2:31 PM

To: Santos, Michae (FNIH) [T] (b) (6)

Cc: Lane, C (ff (NIH/NIAID) [E] · ; Wholley, David (FNIH) [T] (b) (6) Freire, Maria

(FNIH) [T] (b) (6)

Subject: Re: Roster of ACTIV Vaccines WG

Can you do me a favor and just pull out the names and institutions of the people who are not on the Vaccines WG?

Sent from my iPhone

On Oct 10, 2020, at 2:21 PM, Santos, Michael (FNIH) [T] (b) (6) > wrote:

Hi Francis,

We don't maintain as nice of a version of the Sub-Group rosters, but here is the Clinical Trials Sub-Group list of names and organizations (some of which overlap with the main WG). We also commonly have additional guests depending on the topic, so if there's an organization or expertise that you're looking for that is not represented, we can invite them to a meeting ad hoc.

Thanks, Mike

Name	Organization	
Paula Annunziato (co-chair)	Merck	
Larry Corey (co-chair)	Fred Hutch	
Ann Arvin	Stanford	
Beth Bell	UW	
Marco Cavaleri	EMA	
Myron Cohen	UNC	
Elizabeth Desrosiers	Merck	
Macaya Douoguih	J&J	
Peter Dull	Gates	
Emilio Emini	Gates	
Emily Erbeld ng	NIAID/NIH	
Gregory M. Glenn	Novavax	
Peter Gilbert	SCHARP/UW	
Paul Gillard	GSK	

Bill Gruber	Pfizer
Marion Gruber	CBER/FDA
Sanjay Gurunathan	Sanofi
Holli Hamilton	BARDA
Ian Hirsch	AZ
Peter Hotez	Baylor and Texas Children's
Laurent Humeau	Inovio
Kathrin Jansen	Pfizer
Cheryl Keech	Novavax
Kenneth Koury	Pfizer
Michael Kurilla	NCATS/NIH
Julie Ledgerwood	NIAID/NIH
Maarten Leyssen	18:1
Doug Lowy	NCI/NIH
Peter Marks	CBER/FDA
Mary Marovich	NIAID/NIH
Hilary Marston	NIAID/NIH
Stacey Martin	CDC
John Mascola	VRC/NIH
Nelson Michael	WRAIR
Jacqueline Miller	Moderna
Kayvon Modjarrad	WRAIR
Kathleen Neuzil	Maryland
Paul Offit	Penn/CHOP
Ashley Parker	NIH
Merlin Robb	Henry Jackson Foundation
François Roman	GSK
Jerald Sadoff	1&1
Stephanie Schrag	CDC
Sheri Schully	NIH
Sandra Sitar	VRC/NIH
Saranya Sridhar	Sanofi
Jennifer Verani	CDC
Michael Watson	Moderna
Tal Zaks	Moderna

Michael Santos, PhD

Associate Vice President, Science (Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] < (b) (6) **Sent:** Saturday, October 10, 2020 12:47 PM **To**: Santos, Michael (FNIH) [T] < (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] $<\underline{c}$ (b) (6) . Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] (b) (6) **Subject:** RE: Roster of ACTIV Vaccines WG

Thanks, this is helpful. Have you got a roster of the Clinical Trials Sub-Group?

From: Santos, Michael (FNIH) [T] < (b) (6)
Sent: Saturday, October 10, 2020 11:47 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] (b) (6)

Subject: RE: Roster of ACTIV Vaccines WG

Hi Francis,

Sure, I'd be happy to convene a meeting of the WG.

The WG membership is attached We also have a wider group of people that have been part of the subgroups, so depending on the topic and the ask we could invite them as well (e.g., for a clinical trials question we could convene the WG plus the Clinical Trials Sub-Group).

For next steps, if we can know a little more about the topic and the desired timing, I'm happy to connect with Kathrin and Doug and schedule a meeting with the appropriate set of people.

Best regards,

Mike

Michael Santos, PhD

Associate Vice President, Science Foundation for the National Institutes of Health

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Saturday, October 10, 2020 11:33 AM
To: Santos, Michael (ENIH) (T) (b) (6)

To: Santos, Michael (FNIH) [T] (b) (6)

Cc: Lane, Cliff (NIH/NIAID) [E] < (b) (6) . Wholley, David (FNIH) [T] (b) (6)

Freire, Maria (FNIH) [T] (b) (6)
Subject: Roster of ACTIV Vaccines WG

Hi Mike,

We might need to reconvene the ACTIV Vaccines WG for some advice about management of next steps for the trials. Can you send me the roster?

Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

7/1/2020 4:09:11 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collins[]

Subject:

FW: Confirm Attendance: July 1 ACTIV Leadership Call #5

Flag:

Follow up

From: David Meeker < (b) (6)

Sent: Wednesday, July 1, 2020 9:11 AM

To: Wholley, David (FNIH) [T] < (b) (6)

Cc: Melencio, Cheryl (FN H) [T] < (b) (6)

Subject: Re: Confirm Attendance: July 1 ACTIV Leadership Call #5

Apologies David. I will attend. Best. David

Sent from my iPhone

On Jul 1, 2020, at 9:09 AM, Wholley, David (FNIH) [T]

(b) (6)

wrote:

WARNING: This email originated from outside of KSQ. Proceed with caution.

Dear David - Will you be on today's call, and can you please confirm back to Cheryl and me? Thanks, David Wholley

From: Melencio, Cheryl (FNIH) [T] (b) (6)

Sent: Monday, June 29, 2020 1:18 PM

To: Cavaleri, Marco < (b) (6) Cihlar, Tomas (b) (6) Pisbrow, Gary (OS/ASPR/BARDA) < (b) (6) Erbelding, Emily (NIH/NIAID) [E]

(b) (6) >; Gibbons, Gary (NIH/NHLBI) [E] < (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) < (b) (6) ; Lee, William (b) (6) Lepore, John

(b) (6) Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6)

(b) (6) ; Plenge, Robert (b) (6) Reed, John (b) (6) >; Skovronsky, Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6)

Talley, Michael (b) (6) Vessey, Rupert (b) (6) Woodcock, Janet

(FDA/CDER) (b) (6) ; Jansen, Kathrin (b) (6) > Cc: Giorgi, Sara (b) (6) >; Dimishkov, Roxanne (NIH/NHLBI) [C]

(b) (6) MacDougall, Cheryl (b) (6) Thomas, Ashley

(FDA/CDER) (b) (6)

Subject: Confirm Attendance: July 1 ACTIV Leadership Call #5

Good afternoon,

Please confirm your attendance for the ACTIV Leadership Call on Wednesday, July 1-1-2:30 p.m. Eastern time.

Thank you for your assistance.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnin.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: finih org pandemic

<image001 png>

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF)

Sent:

5/18/2020 1:58:04 PM

To:

(b) (6)

CC:

Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

Subject: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

(b) (6)

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you - and yet we wanted to get perm ss on before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] <

Sent: Saturday, May 16, 2020 6:02 PM

To: Collins, Francis (NIH/OD) [E]

(b) (6)

Cc: Myles, Renate (NIH/OD) [E] -Meltzer, Abbey (FNIH) [T] ; Wholley, David (b) (6)

(FNIH) [T] (b) (6)

Subject: URGENT, need your response: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACT V web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please don't delay further, and send your responses to me, coing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

Sent:

5/18/2020 2:27:15 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject:

RE: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Flag:

Follow up

Should we just include her? I need to push the website live.

From: Collins, Francis (NIH/OD) [E] <

(b) (6)

Sent: Monday, May 18, 2020 9:58 AM

To:

(b) (6)

Cc: Myles, Renate (NIH/OD) [E] <

(b) (6)

Subject: NOW REALLY URGENT, need your response: Making your ACTIV Participation Public

Hi Kathrin,

Sorry to keep bugging you, and it's possible we missed seeing your earlier response, but is it OK to list you on the ACTIV web site? As co-chair of the Vaccines WG, it would be very unfortunate to omit you – and yet we wanted to get permission before doing so. We want to post this imminently today.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E]

(b) (6)

Sent: Saturday, May 16, 2020 6:02 PM

To: Collins, Francis (NIH/OD) [E]

(b) (6)

Cc: Myles, Renate (NIH/OD) [E] <

Meltzer, Abbey (FNIH) [T] (b) (6) >, Wholley, David

(FNIH) [T]

(b) (6)

Subject: URGENT, need your response. Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this follow up and increasingly urgent message is for you, even though your address was in the bcc line! We have heard from almost all of the ACTIV Working Group participants, and so far all have been happy to have their names listed in the ACTIV web site. But we still haven't heard from YOU.

Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please don't delay further, and send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 5 p.m. ET tomorrow, Sunday May 17.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 5/1/2020 12:47:20 PM Sent: To: Sranivasan, Badhri [Vincent, Mike [Stein, Peter (b) (6) (b) (6) (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Bascles, Lionel Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry Desrosiers, Betsy [Dickens, Jim (NIH/NCATS) [C] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoi]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; King, James (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce1f3853e43d4463a04f7d74992f96ac-James.K ng]; Kur IIa, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonmal; Resnansky, Laura Wachtel, Jonathan Woodcock, Janet (FDA/CDER) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm] CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Garner, Carlos Coivis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Hughes, Eric (b) (6) Jansen, Kathrin (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4); Anderson, Margaret Carluccio, Dana Melencio, Cheryl (FNIH) [T] (b) (6) (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa742841Sbb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF235PDLT)/cn=Rec pients/cn=user3c2f486d]; Heaton, Penny (b) (6) James, Stephan e (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Tuvesson, Nancy Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholieyd); Criffield, Robin Hamilton, Nancy Minnich, Beth (b) (6) (b) (6)

(b) (6)

Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Thomas, Ashley (FDA/CDER)

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom); Stratton, Benjamin

[(b) (6) Tolman, Brett [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da);

Jintanat Ananworan ch [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda 05012020 pdf; Innovations Matrix 1May2020.xlsx

Location: https://zoom. (b) (6)

Start: 5/1/2020 1:00:00 PM End: 5/1/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Srinivasan, Badhri; Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron, Corey, Larry; Desros ers,

Attendees: Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; King, James;

Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ash ey (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura;

Wachtel, Jonathan; Woodcock, Janet (FDA/CDER); Qashu, Felicia

Optional Sizemore, Christine (NiH/FIC) [E]; Garner, Carlos; Colvis, Christine (NiH/NCATS) [E]; Hughes, Eric, Jansen, Kathrin; Attendees: Lowy, Douglas (NCI); Read Sarah (NiH/NIAID) [E]; Young, John, Adam, Stacey (FNiH) [T]; Anderson, Margaret;

Carluccio, Dana; Cheryl (FNIH) Melencio [T] ((b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose, Menetski, Joseph (FNIH) [T]; Santos, Michae (FNIH); Tuvesson, Nancy; Wholley, David

(FNIH) [T]; Criffield, Robin; Hamiston, Nancy; Minnich, Beth, Rebecca (NIH/NCATS) Katz [E] ((b) (6) Thomas, Ashley (FDA/CDER); Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Attaching the most recent version of the innovations matrix. Karen

Dear Colleagues, Agenda is attached. During this call we will hear the latest from the three sub-WGs – innovations, inventory, and survey – which have been working very hard to move their activities forward quickly. Many thanks to all! We will also have a bit of a brainstorming session about creating a 'dashboard' to use in analyzing survey results. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

Join Zoom Meeting

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                (b) (6)
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Find your local number: https://zoom.us/u (b) (6)
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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Sent:

5/18/2020 2:28:44 PM

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Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-colfinsf]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC:

Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Adam,

Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject:

FW: ACTIV Executive Committee Meeting 202005017dw.pptx

Attachments: ACTIV Executive Committee Meeting 202005018.pptx

For our meeting in three minutes sorry for the late send.

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]

Sent:

7/20/2020 6:42:35 PM

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Subject:

did you get an invite for the July 15 Exec Comm meeting?

Hi Michelle,

It dawned on me too late that I didn't have the July 15 ACTIV Executive Committee Teleconference on my calendar. I got the slides from David in the email below, but I don't think I ever got the invitation. Did you get the invitation? I shouldn't miss the next one.

Thanks, Ellen

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From: Melencio, Cheryl (FNIH) [T] <
                                                           On Behalf Of Wholley, David (FNIH) [T]
                                            (b)(6)
Sent: Tuesday, July 14, 2020 8:44 PM
To: Collins, Francis (NIH/OD) [E] <
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                                                         Disbrow, Gary (OS/ASPR/BARDA) <
                                                                                                       (b) (6)
Dolsten, Mikael <
                                                Fauci, Anthony (NIH/NIAID) [E] <
                                                                                                          Gibbons, Gary
(NIH/NHLBI) [E] <
                                           Marks, Peter (FDA/CBER) <
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Woodcock, Janet (FDA/CDER) <
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Young, John <
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                               James, Stephanie (FNIH) [T] <
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Tolman, Brett <
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Subject: Materials for July 15 ACTIV Executive Committee Teleconference

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 PM to 4:30 PM Eastern U.S. time tomorrow, Wednesday July 15. I have also attached notes from our July 1 Leadership Team meeting as well as our last EC meeting on June 17.

The Zoom meeting information is: Join Zoom Meeting https://fnsh.zoom.us (b) (6) Meeting ID: (b) (6) Password: (b) (6) One tap mobile (b)(6)US (Germantown) US (Chicago) Dial by your location (b) (6) JS (Germantown) JS (Chicago) JS (New York) JS (San Jose) JS (San Jose) JS (Tacoma) JS (Houston) elgium **lgium** elgium elgium elgium Canada Canada :anada Canada Canada rance rance rance rance rance apan apan apan Italy

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Me lors, John W Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Proschan, Michae Read, Sarah (NIH/NIAID) [E] [(NIH/NIAID) [E] [(b) (6) (b) (6) (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter,Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw); Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc); Brown, Jeremy (N-H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp); 8eigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4); .acqueline K rchner Garner, Carl (b) (6) Menon, Sandeep (b) (6) Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [Gottesdiener, Keith (b) (6) Eisner, Mark (b) (6) (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes); Judy Currier

To:

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                                     Stratton, Benjamin [
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                                                                       Qashu, Felicia (NIH/OD) [E]
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [USARMY DOD JPEO CBRND (USA) (b) (6) (b) (6) (b) (6) ACTIV TX-Clinical_Working Group Meeting Guide 20200723.pdf Attachments: Start: 7/23/2020 5:00:00 PM End: 7/23/2020 6:00:00 PM Recurrence: (none) Required Jacqueline Kirchner; Garner, Carl; Menon, Sandeep; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Attendees: Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poote, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E], Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Re neck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Elen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) (b) (6) Optional Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) Attendees: [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio, Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; Molica, Linda /US; Qashu, Felicia (NIH/OD) [E]; (b) (6) Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andre (NIH/NHLBI) [E]: (b) (6) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA) Dear ACTIV TX-Clinical WG members, Please find attached the slides for today's meeting with the agenda. We will have a speaker from NIAID presenting on a new master protocol idea. Thanks, Stacev Join Zoom Meeting https://fnih.zoom.u (b) (6) Meeting ID: (b) (6) Password: (b) (6) One tap mobile US (Germantown) (b) (6) US (Chicago)

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Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

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To:

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1 / 1 /	mer, Andrea (NIH/NIAID) [I		
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Diamond, Michael ((b) (6)			

 Start:
 2/17/2021 3:00:00 PM

 End:
 2/17/2021 4:00:00 PM

Recurrence: (none)

From:

Harris, Kathryn (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLTI/CN=RECIPIENTS/CN=79D72A4A3DCB43E785C83411756CD9E7-HARRISKATH]

Sent:

12/18/2020 8:34:31 PM

To:

CC:

Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]; O'Reilly, Marina (NiH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym] Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject:

RE: ACTIV slides from today on escape mutations

Well BARDA making grantees follow GLs (based on the vaccine stuff they had come to us)

From: Tucker, Jessica (NIH/OD) [E] <

(b)(6)

Sent: Friday, December 18, 2020 3:32 PM To: O Reilly, Marina (NIH/OD) [E] <

(b) (6) Harris, Kathryn (NIH/OD) [C] < (b) (6)

Cc: Gadbois, Ellen (NIH/OD) [E] <

Subject: FW: ACTIV slides from today on escape mutations

More from Ellen on this.

From: Gadbois, Ellen (NIH/OD) [E] <

(b) (6)

Sent: Friday, December 18, 2020 12:11 PM

To: Tucker, Jessica (NIH/OD) [E]

(b) (6)

Subject: RE: ACTIV slides from today on escape mutations

And more from the FNIH/Deloitte call—Moncef Slaoui is going to ask BARDA for the funds for this project. FNIH is prepping a budget.

From: Gadbois, Ellen (NIH/OD) [E]

Sent: Friday, December 18, 2020 10:41 AM

To: Tucker, Jessica (NIH/OD) [E] (b) (6)

Subject: RE: ACTIV slides from today on escape mutations

More today on the ACTIV predinical WG call: FYI this whole effort also includes escape mutants from the vaccines, not just the therapeutics. And I think the member from Roche said something like there are already mutations known to affect efficacy of cocktails (presumably of antibodies), but I am not sure I heard that right. At any rate, I keep hearing the FDA is requiring companies to generate this information.

From: Tucker, Jessica (NIH/OD) [E]

(b) (6)

Sent: Wednesday, December 16, 2020 4:17 PM To: Gadbois, Ellen (NIH/OD) [E]

(b) (6)

Subject: RE: ACTIV slides from today on escape mutations

Thank you!

From: Gadbois, Ellen (NIH/OD) [E]

(b)(6)

To: Tucker, Jessica (NIH/OD) [E] <

Subject: FYI: ACTIV slides from today on escape mutations

Sent: Wednesday, December 16, 2020 1:16 PM

See slides 6-10. Note that slide 8 includes "selection screens." There was general enthusiasm on the call today for the general effort and FC asked industry members what they could do to help. Skip Virgin from VIR said that there are certain experiments that FDA is also asking sponsors to conduct and so centralizing assays and information was important. There was then discussion of a platform that FDA/BARDA/OWS has apparently already built that takes sequence data, makes pseudotype viruses, and run them against a panel of antibodies. (I had to look up pseudotyping—it sounds like it is making a replication incompetent virus.) Not much more detail.

	On Behalf Of Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM	
To: Wholley, David (FNIH) [T] (b) (6) Aus	tin, Christopher (NIH/NCATS) [F] (b) (6)
	Carter, Kara (b) (6) . Cavaleri, Marco
(b) (6) Cihlar, Tomas	
	. Culp, Michelle (NIH/OD) [E] (b) (6)
Victoria Davey (b) (6) Disbrow, Gary	(OS/ASPR/BARDA) < (b) (6) Dolsten, Mikael
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(b) (6) Fauci, Anthony (NIH/NIAID) [E]	(b) (6) >; Freire, Maria (FNIH) [T]
< (b) (6) Gadbois, Ellen (NIH/OD) [E] <	(b) (6) Gibbons, Gary (NIH/NHLBI) [E]
(b) (6) >; Hudson, Thomas <	(b) (6) James, Stephanie (FNIH) [T]
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Marks, Peter (FDA/CBER) (b) (6) >; N	
	Meeker, David (b) (6) Menetski, Joseph
(FNIH) [T] (b) (6) Messonnier, Nancy (CI	OC/DDID/NCIRD/OD) (b) (6) Pandya, Hitesh
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(b) (6) >; Parker, Ashley (NIH/OD) [E]	(b) (6) >; Paul, Steve < (b) (6)
Perlmutter, Roger (b) (6) >; Plea	nge, Robert (b) (6) >; Plump, Andy
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	Santos, Michael (FNIH) [T] < (b) (6)
	n, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
	(b) (c) : Talloy Michael
< (b) (6) >; Tabak, Lawrence (NIH/OD) [E]	(b) (b) , railey, wichael
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Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
[Mth.org
11400 Rockville Pike State 600 North Bethesda, MD 20852

In 2019, the FNIH carned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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                          >; Meltzer, Abbey (FNIH) [T]
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Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020
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Dear ACTIV Leadership Team and meeting attendees:

Canada Canada France France France France

Attached please find the slides for our meeting tomorrow, Wednesday, December 16, 10:00 - 11:30 a.m. Eastern U.S. Time. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Join Zoom Meeting
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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
(nih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20×52

as an organization that exceeds industry standards.

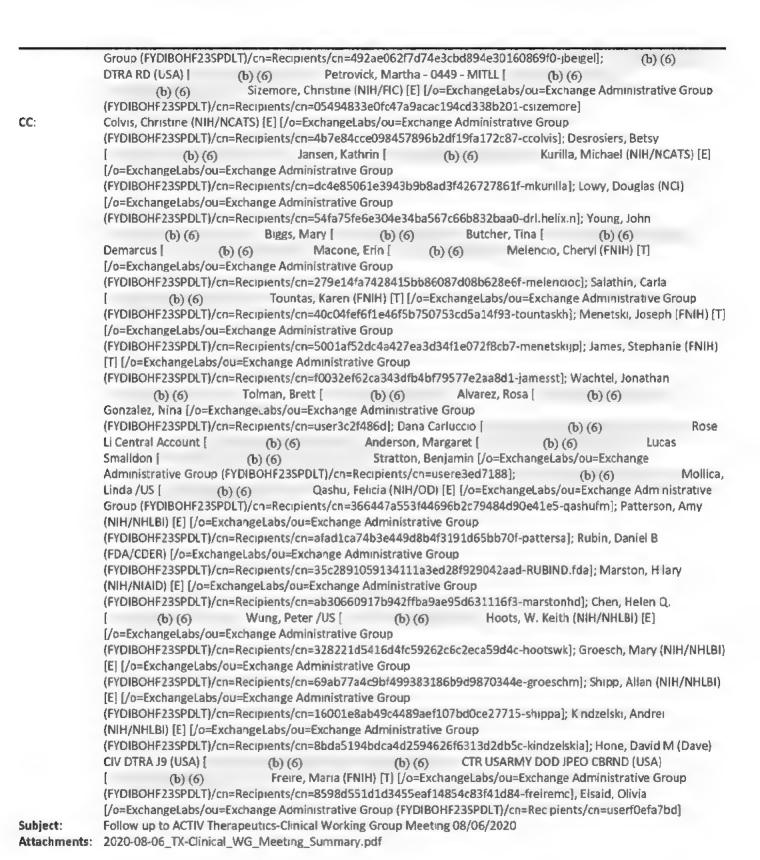
In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized

Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 8/8/2020 1:56:10 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b)(6)Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [(b) (6) Levy, Eliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmrl; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Car : Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Culp, Michelfe (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

From:

Sent:

To:



Dear ACTIV TX-Clinical WG,

Please find attached the summary for our Working Group meeting yesterday. Thank you all for a good discussion on the next steps for the agents and how we can help to promote and enhance our master protocols.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile:

fnin.o.g

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Donale to the FNIH's Pandemic Response Fund to combat COVID-19: 'nih.org pandemic



Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 6/5/2020 12:22:22 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith Hughes, Eric **Judy Currier** (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m}; Kim, Elizabeth LaVange, Lisa (b) (6) Levy, Elliot Mellors, John W (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep [Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish]; Peppercorn, Amanda [Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Shen, Yuan Li (FDA/CDER) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim. (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli), Amanda Peppercorn (b) (6) Garner, Carl (b) (6) . Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey); Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N.H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel); Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Jacqueline Kirchner (b) (6)

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Subject:	Initia Follow-up to AC	TIV TX-Clinical Working	Group Meeting #5	9			

Dear ACTIV TX-Clinical WG,

Thank you all for the good discussion and feedback on the master protocols on today's call.

As promised as part of my initial follow up to the meeting, please find below the now active link for agent survey submissions.

https://redcap.ncats.nih.gov/redcap/surveys/index.php?s=DAE87WPTE7&

Please feel free to use this for any agents your companies may wish to have considered or share it with any other colleagues who think may have something interesting for us to consider.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk); Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Walker, Paula
(NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                 Jansen, Kathrin
                                                                          Kurilla, Michael (NIH/NCATS) [E]
                                                          (b) (6)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
                           Biggs, Mary
                                                              Butcher, Tina
                                               (b) (6)
Demarcus [
                                    Macone, Erin [
                                                                     Melencio, Cheryl (FNIH) [T]
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                          ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}, Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group]
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group]
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
                       Tolman, Brett
                                                            Alvarez, Rosa [
                                                                                                  Dana
        (b) (6)
                                             (b) (6)
                                                                                  (b) (6)
Carluccio i
                                             Rose Li Central Account
                       (b) (6)
                                                                                              Margaret
                                                                              (b) (6)
Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group]
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso], Lucas Smalidon
                                     Stratton, Benjamin [
               (b) (6)
                                                                (b) (6)
                                                                       Qashu, Felicia (NIH/OD) [E]
                            Mollica, Linda /US [
          (b) (6)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa); Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                        Wung, Peter /US [
                                                                 Hoots, W. Keith (NIH/NHLBI) [E]
                                                 (b) (6)
         (b) (6)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [**USARMY DOD JPEO CBRND (USA)** (b) (6) Elsaid, Olivia [Walker, Paula (NIH/NINDS) [E] (b) (6) (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes Sorosa, Alex David Freire, Maria (FNIH) [T] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, N na [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d] 10/15/2020 5:00:00 PM Start: End: 10/15/2020 6:00:00 PM Show Time As: Busy Recurrence: (none) Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom.us/ (b) (6) Meeting ID: (b) (6) Password: (b) (6) One tan mobile (b)(6)US (Germantown) US (Chicago) Dial by your location (b) (6) US (Germantown) US (Chicago) US (New York) US (Tacoma) US (Houston) US (San Jose) US (San Jose) Meeting ID: (b) (6) Password: (b) (6) Find your local number: https://fmih.zoom.us/u (b) (6)

Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange

To:

CC:

(b)(6)

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski Baric, Toni C (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh); Stratton, Benjamin (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison Mason, Stephen [Connelly, Sarah ((b) (6) (b) (6) (b) (6) https://fnih.zoom.us/ Location: (b) (6) Start: 10/21/2020 2:15:00 PM End: 10/21/2020 3:00:00 PM Show Time As: Tentative Recurrence: (none) every Wednesday from 10:00 AM to 11:00 AM Required Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) Attendees: (b) (6) (b)(6)(b)(6)(b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; (b) (6) USARMY MEDCOM USAMRIID (USA); Punturiers, Antonello (NIH/NHLBI) [E]; Tomas Cihlar; (b) (6) Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Optional (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher Attendees: (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michae (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth, Tolman, Brett, Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E], Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C, Lowy, Doug as (NIH/NCI) [E]; Forence, Clint (NIH/NIAID) [E], Nancy Haigwood; Stratton, Benjamin, Gadbois, Ellen (NIH/OD) [E], Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah

Connelly, Sarah [(b) (6) 11/6/2020 2:29:28 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai), Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea}; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Dem ng, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria); Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Diamond, Michael (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Reapients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd); Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Desros ers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes); Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa); Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user706e5647]; Kim, btolman [/o=ExchangeLabs/ou=Exchange Administrative Group Elizabeth [(b) (6)

From:

Sent: To:

CC:

GADB0000001846-2516914



Dear Preclinical working group,

Next week's full working group meeting falls on Veterans Day. Would the group prefer keeping the meeting on Wednesday at its regularly scheduled time or moving it to 10-11 ET Thursday, Nov 12, 2020?

Can you please let us know which of these options work for you. We will move the meeting to the most popular option.

Best regards, Sarah

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Sarah Connelly, PhD
Deloitte Consulting, LLP
                 (b) (6)
Tel/Direct:
www.de.artte.com
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----Original Appointment-----
From: Menetski, Joseph (FNIH) [T] <
                                           (b) (6)
Sent: Friday, October 2, 2020 2:19 PM
To: Menetski, Joseph (FNIH) [T];
                                                              Hild, Sheri (NIH/OD) [E];
                                            (b) (6)
                                                                                                (b) (6)
             (b) (6)
                                           (b) (6)
                                                                     (b) (6)
                                                                                               (b) (6)
                                                             Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine
    (b) (6)
                Baric, Ralph;
                                          (b) (6)
(NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);
                                                                                          (b) (6)
                                             Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];
     (b) (6)
                            (b) (6)
              (b) (6)
                                   Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas
Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc
(NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];
                                                        (b) (6)
Cc: Diamond, Michael; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E], Melencio, Cheryl (FNIH) [T],
Desrosiers, Betsy; Eric Hughes, Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah
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(NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH)

[T]; A varez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E], Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b) (6) Connelly, Sarah;

Subject: ACTIV Preclinical full working group

When: Thursday, November 5, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: https://fnih.zoom.us/ (b) (6)

While not unanimous, more people were able to make the 5th at 10am. We will go over the discussion at the Executive committee meeting, future strategic topics and then our normal reviews.

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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                     US (Chicago)
                     US (New York)
                     JS (San Jose)
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Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLTI/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC) 10/22/2020 1:39:56 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Baric, Ralph (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e3Sab1d3044465a7790ee4ded5bc32-rbaric.email, Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, .udith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Dem ng, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; ; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria); Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melengoc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskhi; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4); .ames, Stephanie (FNIH) [T]

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Elizabeth [(b)	(6) btolmar	[/o≃ExchangeLa	bs/ou=Exchang	e Adminis	trative Group	
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(NIH/NCATS) [E] [/o=E	xchangeLabs/ou=E	xchange Admini	strative Group			
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Mason, Stephen [(b) (6)	Connelly,	Sarah (/o=Exch	angeLabs/	ou=Exchange A	Administrative
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Re: ACTIV Preclinical f	ull working group					

ACTIV Preclinical WG -

Subject:

Thanks!

Clint Florence, Ph.D.
Program Officer, Office of Biodefense, Research Resources, and Translational Research
NIH/NIAID/DMID/OBRRTR/RRS
Room 8G56
5601 Fishers Lane
Rockville, MD 20852
Tel: (b) (6)
cell: (b) (6)

From:	"Florence, Clini	t (NIH/NIAID) [E]" <	(b) (6)			
Date: 1	Wednesday, Oc	tober 21, 2020 at 12	:47 PM			
To: "M	lenetski, Joseph	(ENIH) [T]"	(b) (6)	"john.	(b) (6)	
<	(b) (6)	"kara.	(b) (6)	<	(b) (6)	"Hild, Sheri (NIH/OD)
[E]" <	(b) (6)	¹¹ (b) (6) <	(b)	(6)	
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(NIH/N	IIAID) [E]" <	(b) (6)	"Deming, Dar	mon (FDA/	CDER)" <	(b) (6)
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13	(b) (6)	< (t) (6)	"Parker,	Ashley (NIH/OD)	[E]"
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<	(b) (6)	Tomas Cihlar <	(b) (d	5)	"Pitt, Margaret	L CIV USARMY MEDCOM
USAM	RIID (USA)" <	(b) (6)	"Punt	urieri, Anto	nello (NIH/NHLBI) [E] ¹¹
<	(b) (6)	"Charette, N	Marc (NIH/NH	LBI) [E]" <	(b) (6)	"Fessel, Josh
(NIH/N	IHLBI) [E]" <	(b) (6) "	(b) ((6)	< (b)	(6)
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[E]" < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) "Desrosiers, Betsy" < (b) (6) Eric Hughes < (b) (6) "Jansen, Kathrin" < (b) (6) "Kurilla, Michae (NIH/NCATS) [E]" < (b) (6) "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Santos, Michael" (FNIH) [T]" < (b) (6) "Adam, Stacey (FNIH) [T]" < (b) (6) "James, Stephanie (FNIH) [T]" < (b) (6) "Alvarez, Rosa Maria" < (b) (6) "Kim, Elizabeth" btolman < (b) (6) "Wachtel, Jonathan" < < (b) (6) (b) (6) Prabhavathi Fernandes < (b) (6) "Diamond, Michael" < (b) (6) Dana Carluccio < (b) (6) Rose Li < (b) (6) "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6) "Jonson, Samantha (NIH/NCATS) [E]" < (b) (6) "Gonzalez, Nina" < (b) (6) "Simon, Dina (NIH/OD) [C]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" < (b) (6) "Rodriguez, Robin" D" < (b) (6) Dave Frankowski < (b) (6) "Baric, Toni C" (b) (6) "Lowy, Douglas (NIH/NCI) [E]" < (b) (6) "Florence, Clint (NIH/NIAID) [E]" < (b) (6) Nancy Haigwood < (b) (6) "Stratton, Benjamin" < (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Anderson, James (b) (6) "Hawk, Harrison" < (b) (6) "Mason, Stephen" (NIH/OD) [E]" < < (b) (6) "Connelly, Sarah" < (b) (6) (b) (6) < (b) (6)

Subject: Re: ACTIV Preclinical full working group

ACTIV Preclinical Group -

(b)(4)

Thanks -

Clint

From: (b) (6)

When: 10:15 AM - 11:00 AM October 21, 2020 Subject: ACTIV Preclinical full working group

Location: https://fnih.zoom.us/ (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 7/23/2020 8:52:26 PM Sent: To: Bascles, Lionel Cohen, Myron [/o=ExchangeLabs/ou=Exchange Adm nistrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksul; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonmal; Resnansky, Laura Sizemore, Christine (NH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]: Takas, Therese Vincent, Mike Weinmann, Gail (NIH/NHLBI) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang) CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Wachtel, Jonathan [(b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n), Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Ardiff, Bernadette (b) (6) Criffield, Robin Hamilton, Nancy [Melencio, Cheryl (FNIH) [T] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [bminnich@fredhutch.org]; Mueller-Reichenstein, Petra [Pico, Dianna (b) (6) (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-p codf]; Quadros, Nora m]; Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd], H II, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs], Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Admin strative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Heaton, Penny (b) (6)

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	Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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On Fri, Ju	n 5, 2020 at 8:2	8 PM Menetski, Jose	epn (FNIH)[1]	(b) (6)	wrote:	
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Dear Pred	ilinical working	g group and attendee:	s,			
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		_	Wednesday. Thank yo	ou for an inici	resting meeti	ng and let me
know if y	ou nave any qu	estions or comments	on the notes.			
Thoulson						
Thank yo	u,					
Joe						
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From: M	lenetski, Joseph	(FNIH) [T]				
Sent: Tue	esday, April 14.	, 2020 6:43 PM				
To:	(b) (6)		(b) (6)			; Rao, Srinivas;
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Cc: Florence, Clint (NIH/NIAID) [E]; Simon, Dina (NIH/OD) [C]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanic (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Ton: C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical working group (Tuesday meeting)

When: Wednesday, June 3, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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John A.T. Young, PhD

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Connelly, Sarah [(b) (6) 1/21/2021 6:19:04 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NiH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa); m; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group] (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai), Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea}; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Dem ng, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desros ers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla}; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams[4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabnavathi Fernandes Diamond, Michael [Rose Li (b) (6) (b) (6)

From:

Sent:

To:

CC:

	(b) (6)	Dana Carluccio [(b) (6)	Lagos, Enrique (NIH/NCATS)
	[E] [/o=ExchangeLabs/ou	=Exchange Administrative Gro		
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=ae9041ab27204	4d83b06752f67a44b0d1	-lagoses]; .onson, Samantha
	(NIH/NCATS) [E] [/o=Excl	hangeLabs/ou=Exchange Admi	nistrative Group	
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=ce2f69369d654	bef89b0d39b145d69a7-	jonsonsg]; Gonzalez, Nina
	[/o=ExchangeLabs/ou=Ex	change Administrative Group	(FYDIBOHF23SPDLT)/cn:	=Rec pients/cn=user3c2f486d];
	Simon, Dina (NIH/OD) [C]] [/o=ExchangeLabs/ou=Exchai	nge Administrative Grou	р
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=e02345fa5d1d4	d7eaf4e0f3da58bc1ac-s	simondm); Burrus-Shaw, Cyndi
	(NIH/OD) [E] [/o=Exchang	geLabs/ou=Exchange Administ	rative Group	
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=5bbac95b1f6e4	514a299b318030c31f6-	shawcy); Rodriguez, Robin D
	(b) (6)	Dave Frankowski [(b) (6)	antoinette_baric
	[/o=ExchangeLabs/ou=Ex	change Administrative Group	(FYDIBOHF23SPDLT)/cn	=Recipients/cn=userb6b844cf]; Lowy,
	Douglas (NIH/NCI) [E] [/c	=ExchangeLabs/ou=Exchange	Administrative Group	
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=f1b7b8fe47394	78bb17840c56902718a-	lowyd]; Florence, Clint (NiH/NIAID)
	[E] [/o=ExchangeLabs/ou	=Exchange Administrative Gro	up	
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=5e032d0bc8554	le8787e844a7773295fe	-florencewc]; Nancy Haigwood
	[/o=ExchangeLabs/ou=Ex	change Administrative Group		
	(FYDIBOHF23SPDLT)/cn=	Recipients/cn=03d589f440d84	691ac0a530e4ba6ceb5	-haigwoon.oh); Gadbois, Ellen
		geLabs/ou=Exchange Administ	-	
		Recipients/cn=0243d1d6e6f24		gadboisel]; Anderson, James
	,	geLabs/ou=Exchange Administ		
				l-andersonjm]; Hawk, Harrison
	**	change Administrative Group	(FYDIBOHF23SPDLT)/cn:	=Rec pients/cn=user280c84f8];
	Mason, Stephen [(b) (6)	(b) (6)	(b) (6)
		CATS) [C] [/o=ExchangeLabs/o		
		Recipients/cn=1be900c2388d4	l1f48e3f2cbcb2fed349-l	umsden;m); K C Kent L oyd
	(b) (6)	(b) (6)		
ubject:	RE: ACTIV Preclinical full			
ttachments:		mit_Report_508.pdf; 2021-01	-20_Preclinical_WG_vF.	pdf; Precimical WG_Subgroup
	Updates.pptx			
ear Preclinic	cal Working Group,			
	9			
hank you all	for attending our ACTIV	preclinical full working gro	up meeting yesterday	. Please see attached for the note:

from our discussion, and let us know if you all have any additions or amendments. We have also attached a slide with the subgroup updates we didn't get to during the meeting.

Also attached please find the finalized report for the SARS-CoV-2 summit on antiviral drug development. Sharing with the WG for awareness.

Best Regards, Sarah

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Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct:
                 (b) (6)
www.deio-tte.com
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----Original Appointment----From: Menetski, Joseph (FNIH) [T] < (b) (6) Sent: Friday, October 2, 2020 2:19 PM To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph; jay (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b)(6)Adams, Peter

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(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM
USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];
          (b) (6)
                                     (b) (6)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric
Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas,
Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T], James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;
Kim, Elizabeth; Tolman, Brett, Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio;
Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-
Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E];
Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James
(NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;
                                                                (b) (6)
                                                                                        Connelly, Sarah;
                   Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd;
                                                                               (b) (6)
Subject: ACTIV Preclinical full working group
When: Wednesday, January 20, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/
                                                         (b) (6)
Changing time for preclinical WG
Joseph Menetski is inviting you to a scheduled Zoom meeting.
Join Zoom Meeting
https://fnih.zoom.us/
                                                 (b) (6)
Meeting ID:
                (b) (6)
Passcode: (b) (6)
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                                               US (Germantown)
                                               US (Chicago)
Dial by your location
         (b) (6)
                     US (Germantown)
                     US (Chicago)
                     US (New York)
                     JS (San Jose)
                     US (San Jose)
                     US (Tacoma)
                     US (Houston)
Meeting ID:
                (b) (6)
Passcode: (b) (6)
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v.E.1

From: Gadbois, El en (N H/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]

Sent:

2/17/2021 4:42:43 PM

To:

Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]; .essica (NIH/OD) Tucker

[E] ((b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]

Subject: more on Baric mouse model

Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team

Meeting_APPENDIX_20210216_vF.pdf; 2021-01-

14 ACTIV Leadership Team and Executive Committee Meeting_Summary vF.pdf

Slides include Baric's long hauler mouse model and testing plans. John Young is presenting to the Leadership Team now.

From: Melencio, Cheryl (FNIH) [T] < (b) (6)	In Behalf Of Wholley, David (FNIH) [T]
Sent: Tuesday, February 16, 2021 7:03 PM	
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6)	
< (b) (6) Carter, Kara <	(b) (6) Cavaleri, Marco
< (b) (6) Cihlar, Tomas <	(b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6) Corey, Larry < (b) (6)	Culp, Michelle (NIH/OD) [E] < (b) (6)
Victoria Davey < (b) (6) Disbrow, Gary (0)	S/ASPR/BARDA) < (b) (6) Dolsten, Mikael
< (b) (6) Embry, Alan (NIH/NIAID) [E]	< (b) (6) Erbelding, Emily (NIH/NIAID) [E]
	Fauci, Anthony (NIH/NIAID) [E] < (b) (6)
Freire, Maria (FNIH) [T] < (b) (6) Gadbois, Ellen	(NIH/OD) [E] < (b) (6) Gibbons, Gary
(NIH/NHLBI) [E] < (b) (6) Hudson, Thomas	< (b) (6) James, Stephanie (FNIH) [T]
< (b) (6) Johnson, Robert (OS/ASPR/BARDA) <	(b) (6) Kramer, Lynn
< (b) (6) Lane, Cliff (NIH/NIAID) [E] <	(b) (6) Lepore, John < (b) (6)
	scola, John (NIH/VRC) [E] < (b) (6) Meeker,
David < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy
(CDC/DDID/NCIRD/OD) < (b) (6) Pandya, Hitesh	< (b) (6) Pangalos, Mene
< (b) (6) Pao, William <	(b) (6) Parker, Ashley (NIH/OD) [E]
< (b) (6) Paul, Steve < (b) (6)	Perlmutter, Roger < (b) (6)
Plenge, Robert < (b) (6) Plump, Andy <	(b) (6) Rachel Ramoni
< (b) (6) Reed, John < (b) (6)	Rease David (b) (6) Rouse Daris
(0) (0)	Reese, David (b) (c) Rouse, Doris
< (b) (6) Santos, Michael (FNIH) [T] < (b) (6)	Skovronsky, Daniel < (b) (6)
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(b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffe [E] < (b) (6) Talley, Michael Vessey, Rupert < (b) (6) Virgin, Skip Woodcock, Janet (FDA/OC) < (b) (6) Christine (NIH/NCATS) [F] < (b) (6) Desn Hughes < (b) (6) Jansen, Kathrin < (b) (6) Lowy, Douglas (NCI) < (b) (6) Young, John < (b) (6)	Skovronsky, Daniel < (b) (6) els, Paul < (b) (6) Tabak, Lawrence (NIH/OD) (b) (6) Tsai, John < (b) (6) (b) (6) Wholley, David (FNIH) [T] < (b) (6) Young, John < (b) (6) Colvis, osiers, Betsy < (b) (6) Eric (b) (6) Kurilla, Michael (NIH/NCATS) [E] (6) Read, Sarah (NIH/NIAID) [E] < (b) (6)
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Menetski, Joseph (FNIH) [T] < (b) (6) Nasr, Hana < (b) (6) Santos, M chael (FNIH) [T] Stratton, Benjamin < (b) (6) Sorosa, Alex < (b) (6) (b) (6) Wholley, David (FNIH) [T] Brett < (b) (6) Wachtel, Jonathan < (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Meltzer, Abbey (FNIH) [T] < Myles, Renate (NIH/OD) [E] < (b) (6) (b) (6) (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b)(6)

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting, tornorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time. The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnin.org

11400 Rockville Pike State 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as un organization that exceeds industry standards.

From: Melencio, Chery! (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC1 Sent: 8/18/2020 3:11:23 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Austin, Christopher (NIH/NCATS) [E] [austinc@mail.nih.gov]; Bancel, Stephane [(b) (6) Carter, Kara Cavaleri, Marco [Cihlar, Tomas (b) (6) (b) (6) [tomas.cinlar@gi ead com]; Collins, Francis (NIH/OD) [E] []: Corey, Larry [(b)(6)(b) (6) Culp, Michelle (NIH/OD) [E] [Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) (b) (6) Dolsten, Mikael Erbelding, Emily (NIH/NIAID) (E) [Erck, Stan (b) (6) (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Gibbons, Gary (NIH/NHLBI) [E] [Hudson, Thomas [James, Stephanie (FNIH) (b) (6) (b)(6)[T] [Johnson, Robert (OS/ASPR/BARDA) [Kramer, Lynn (b) (6) (b)(6)(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) Marston, Hilary (NIH/NIAID) [E] [Mascola, John (NIH/VRC) [E] (b) (6) (b) (6) Meeker, David [Menetski, Joseph (FNIH) [T] (b)(6)(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) | Pandya, Hitesh (b) (6) (b)(6)[h tesh pandya@astrazeneca com]; Pao, William [will Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) Perimutter, Roger [(b) (6) Plenge, Robert (b) (6) Plump, Andy [(b) (6) Rachel Ramoni (b) (6) Reed, John ; Rouse, Doris Santos, Michael (FNIH) [T] [(b) (6) (b) (6) (b) (6) Skovronsky, Daniel [Stein, Peter (FDA/CDER) ; Stoffels, Paul (b) (6) (b) (6) Tabak, Lawrence (NIH/OD) [E] []; Talley, Michael (b) (6) (b) (6) (b)(6)Tsai, John [(b) (6) Vessey, Rupert ((b) (6) 1: Virgin, Skip ((b) (6) Wholley, David (FNIH) [T] [(b) (6) Woodcock, Janet (FDA/CDER) Young, John [Colvis, Christine (NIH/NCATS) [E] (b) (6) (b) (6) Desrosiers, Betsy [**Eric Hughes** (b) (6) (b)(6)Jansen, Kathrin [Kurilla, Michael (NIH/NCATS) [E] (b) (6) (b) (6) (b) (6) Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] Adam, Stacey (FNIH) [T] [Alvarez, Rosa Maria [(b) (6) (b) (6) (b) (6) Chen, Helen Q. [Elsaid, Olivia Margaret Anderson [(b) (6) (b) (6) Gonzalez, Nina [Hawk, Harrison | (b) (6) (b) (6) (b) (6) btolman [Tountas, Karen (FNIH) [T] Stratton, Benjamin [(b) (6) (b) (6) (b) (6) Wachtel, Jonathan [(b)(6)Anderson, James (NIH/OD) [E] Castilleios, Carlos I **FNIH** (b) (6) (ര) (ര (b)(6)Central Account (b)(6)Hallett, Adrienne (NIH/OD) [E] [(b)(6)]; Myles, Renate (NIH/OD) [E] [Wolmetz, Carrie (NIH/OD) [E] []; Appell, Evan (b) (6) (b) (6) Sorosa, Alex [(b) (6) Connelly, Sarah [Fauci, (b) (6) (b) (6) Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lepore, John Pangalos, Mene Paul, Steve [[john.]. (b)(6)(b) (6) Rasi, Gu do [Reese, David ((b) (6) (b)(6)CC: Austin, Sarah (NIH/NIAID) [E] [Barasch, Kimberly (NIH/NIAID) [C] (b) (6) Bell, Julie [Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) (b) (6) (b) (6) Carver, Trea (NIH) [C] ; Caulfied, Anita [Coan, (b) (6) (b) (6) Conrad, Patricia (NIH/NIAID) [E] [.gov], Dimishkov, Roxanne Amanda l (b) (6) (b) (6) (NIH/NHLBI) [C] [(b) (6) Fuhrer, Nicole (b) (6) Giorgi, Sara Isara. Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemai, Vaide (b) (6) Jenkins, Christine S. [Lagos, Enrique (NIH/NCATS) [E] (b) (6) (b)(6)]; Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] (b) (6) Minnich, Beth [Perala, Mie (b) (6) (b) (6) (b) (6) Protasiewicz, Ann [Riccobene, Kim [Riggin, Mary (b) (6) (b) (6) Ripley, Nadege [Schuster, Donna (b) (6) (b) (6) Sepulveda, Dorina (FNIH) [T] [Simon, Dina (NIH/OD) [C] (b)(6)(b) (6) (b) (6)]; Suhana, Tina (NIH/VRC) [E] [(b) (6)]; Thomas, Ashley (FDA/CDER) Wood, Gretchen (NIH/OD) [E] |]; Togashi, Mieko (NIR/NCI) [E] (b) (6)

]; Underwood, Nancy [Zottoli, Jessica (b) (6) (b) (6) Regan, Donna M [(b) (6) Hamilton, Nancy (b) (6) Dana Carluccio | (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [Plenge, Robert (b) (6) (b) (6) Vessey, Rupert [Victoria Davey 1; (b) (6) (b) (6) (b)(6)Burklow, John (NIH/OD) [E] [Harris, Melissa (NIH/OD) [E] []; Kuethe, (b) (6) (b)(6)Christine (OS/ASPR/BARDA) (CTR) [Edl, Susan [Hoban, Michele (b)(6)(b) (6) (b)(6)

Subject:

ACTIV Leadership Call #9

Location:

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Start: End: 10/21/2020 1:15:00 PM 10/21/2020 2:15:00 PM

Show Time As: Busy

Required Attendees: Melencio, Cheryl (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavalen, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael, Erbelding, Emily (NIH/NIAID) [E], Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Elen (N H/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER) Marston, H lary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip, Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Stratton Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Appell, Evan; Sorosa, Alex; Connelly, Sarah

Optional Attendees:

Austin, Sarah (NiH/NIAID) [E], Barasch, Kimberly (NiH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NiH/OD) [E]; Carver, Trea (NiH) [C]; Caulfied Anita; Coan, Amanda; Conrad, Patricia (NiH/NIAID) [E]; Dimishkov, Roxanne (NiH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara, Hoban, Michelle, Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NiH/NCATS) [E]; tever, Susan; McManus, Ayanna (NiH/OD) [E]; Minnich, Beth, Perala, Mie; Protasiewicz, Ann; Riccobene, Kim, Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) (E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Hamilton, Nancy; Dana Carluccio; (b) (6) Lowy, Douglas (NIH/NCI) [E]; Plenge, Robert; Vessey, Rupert; Davey, Victoria, Burklow, John (NIH/OD) [E] (b) (6) Harris, Melissa (N H/OD) [E]; Kuethe, Christine (OS/ASPR/BARDA) (CTR)

Due to an unavoidable conflict for Dr. Collins, it is necessary to move this call from 12:00 p.m. to 9:15 a.m. Thank you.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth
(NIH/NCATS [E] [
                                       Colvis, Christine (NIH/NCATS) [E] [
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(NIH/NIAID) [E]
                              Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative
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(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Adams, Peter
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter Adams]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject:

Required

Start:

End:

Optional Attendees: Lerner, Andrea (NIH/NIAID) [E]; Gonzalez, Nina; Florence, Clint (NIH/NIAID) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]: Jonson, Samantha (NIH/NCATS) [E], Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Nancy Haigwood; Stratton, Benjam n; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; Connelly, Sarah; (b) (6) Lumsden, Joanne (b) (6) (NIH/NCATS) [C]; K C Kent Lloyd; kca Embry, Alan (NIH/NIAID) [E] (b) (6)

The cochairs would like to cancel today and encourage you to join the WHO meeting below

WHO will host a **Global consultation on COVID-19 therapeutics** to discuss knowledge gaps and research priorities, with the following objectives to outline:

- the main priority research questions of importance to public health and a targeted research agenda for 2021 that identifies knowledge gaps and prioritization pathways for therapeutics in clinical development phase and those being repurposed, including combinations, and research priorities for new COVID therapeutics; and
- additional steps to ensure further international collaboration supports the coordinated implementation of key research.

The webinar will be convened on Wednesday, 3 March 2021, 13:30 – 18:30 Central European Time (CET). The proposed agenda will be provided in advance.

Please register on the link below to receive your connection details.

https://who-e.zoom.us/webinar/register/WN/CNfywAEiTEWgqA/nEcjeow

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 12/17/2020 4:00:45 PM Garner, Carl Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith (b)(6)Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [(b) (6) Levy, Eliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish [naimish. Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman); Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli]; Amanda Peppercorn Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla); Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey); Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NiH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp), Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV

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CC:

Subject: **ACTIV Therapeutics-Clinical Working Group Meeting**

Attachments: ACTIV_TX-Clinical WG Meeting_20201217.pdf

Location: https://fnih.zoom.us/ (b)(6)

Start: 12/17/2020 6:00:00 PM End: 12/17/2020 7:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees:

Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda, Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Waiter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E];

Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Garner, Carl; Bozzette, Sam (NIH/NCATS) [E], Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli,

Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

Sizemore, Christine (NIH/FIC) [E]

Optional Attendees:

Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Safathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account; Margaret Anderson; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qasnu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E], Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzerski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa,

Alex David; Lumsden, Joanne (NIH/NCATS) [C]

Dear ACTIV TX-Clinical WG Members,

Please find attached the slides for today's presentation.

Thanks, Stacey

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                         Jeneffer Haynes
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Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLTI)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC1 7/1/2020 3:39:02 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (N:H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; m; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e3Sab1d304446Sa7790ee4dedSbc32-rbaric.emai], Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, .udith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Wholley, David (FNIH) [T] [/o=Exchange_abs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd); Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy Hughes, Enc [Jansen, Kathrin (b) (6) (b) (6) Kurılla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams[4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria Kim, Elizabeth [Tolman, Brett [Wachtel, (b) (6) (b) (6) (b) (6)

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Jonathan Prabhavathi Fernandes [Rose Li (b) (6) (b) (6) Dana Carluccio 1 Lagos, Enrique (NIH/NCATS) (b)(6)(b) (6) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski [Baric, Toni C (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh); Stratton, Benjamin], Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonim]; Diamond, Michael [Subject: Re: ACTIV Preclin cal full working group Attachments: 2020 06 20.137687v1.full.pdf U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant. In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented. Might be of benefit in the EXE meeting tonight. Just an FYI. From: (b) (6) When: 10:00 AM - 11:00 AM July 1, 2020 Subject: ACTIV Preclinical full working group Location: https://fnih.zoom.us (b)(6)Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom. (b) (6) Meeting ID: (b) (6)

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Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 6/15/2020 5:04:44 PM Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email. Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Dem ng, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; ken.duncan@gatesfoundation.org; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Qashu, Felicia (NH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Tomas Cihiar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) | (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiena]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, .osh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp] Diamond, Michael [Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-fiorencewc]; Simon, Dina (NiH/OD) [C] [/o=Exchange_abs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Hughes, Eric (b) (6) Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskhi; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group]

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI8OHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Heaton, Penny James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michae (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Tuvesson, Nancy Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd); Criffield, Robin (b) (6) Hamilton, Nancy [M nnich, Beth (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group bminn (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin Tolman, Brett (b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da); Jintanat Ananworan ch [(b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting

Attachments: Clinical Trial Capacity Working Group Meeting Agenda 05222020 pdf; ACTIV Protocol Tracker 05212020.pdf

Location: https://zoom.us/ (b) (6)

Start: 5/22/2020 1:00:00 PM **End:** 5/22/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Vincent, Mike; Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C];

Attendees: Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker,

Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura, Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel,

Jonathan; Qashu, Felicia

Optional Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot, Weinmann, Gai (NIH/NHLBI) [E]; Mensah, George (NIH/NHLBI) [E]; Attendees: Garner, Carlos; Denny, Joshua (NIH/OD) [E]; Reid, Nancy (NIH/OD) [C]; Gebo, Kelly (NIH/OD) [G], Moschetti, Justin

(NIH/OD) [E]; Cuip, Michelle (NIH/OD) [E]. Gadbois, Ellen (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin, Lowy, Douglas (NCI), Read, Sarah (NIH/NIAID) [E]; Young, John, Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ((b) (6) Francis Collins; Gonzalez,

Nina; Heaton, Penny; James, Stephanie; L., Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E]

(b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, Attached is the Agenda. Please note that we will be hearing from the All of Us program and how they might be useful for implementing ACTIV protocols. In addition, per a request from Tuesday's meeting, attached is the ACTIV Protocol Quick Reference Tracker—thanks to Jonathan and his colleagues for creating this! At present there are three ACTIV protocols, all in the treatment category. CTC Recommendations Committees have been established for the ACTIV-1 and ACTIV-2 protocols to-date and integration with the protocol development and lead network operations teams will take place in the very near future. Best regards, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but

understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager Foundation for the National Institutes of Health

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US (Houston) US (San Jose) US (San Jose) US

Meeting ID: (b) (6) Password: (b) (6)

Find your local number: https://zoom.us/ (b) (6)

To:

Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc4/a9acac194cd338b201-csizemore], Dodd, Lori (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2964312396745bcbf1253d1787f5222-doddl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Sorosa, Alex David Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary (b) (6) Butcher, Tina Demarcus i Macone, Enn [Melencio, Cheryl (FNIH) [T] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathín, Carla Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp|; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett (b) (6) Alvarez, Rosa (b) (6) Gonzalez, Nina Dana Carluccio Rose Li Central (b) (6) (b) (6) Account [Lucas Smalldon [Stratton, Benjamin (b)(6)(b)(6)Mollica, Linda /US [Qashu, (b) (6) (b) (6) (b) (6) Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen. Helen Q. Wung, Peter /US Hoots, W. Keith (NIH/NHLBI) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Alian (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2dbSc-kindzelskia); Hone, David M (Dave) CIV DTRA J9 (USA) [Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Elsaid, Olivia [Walker, Paula (NIH/NINDS) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes Giovanni, Maria (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f55f988ba38456bbcb93f381548c104-mgiovann); Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc)

Start: 10/8/2020 5:00:00 PM End: 10/8/2020 6:00:00 PM

CC:

Recurrence: (none)

Required Attendees: Rosenthal, Alex (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Ange o (FDA/CDER); Draghia-Ak I, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Ell ot; Mellors, John; Menon, Sandeep; Parker, Ashiey (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E], Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, Li Revell CIV DTRA RD (USA); Petrovick, Martha - O449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Dodd, Lori (NIH/NIAID) [E]

Optional Attendees:

Merr tt, Gabriella Marie; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio, Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E], Chen, Helen Q; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Giovanni, Maria (NIH/NIAID) [C]

Sent: 6/22/2020 6:52:55 PM

Subject: FW: Notes from our ACTIV Executive Committee call on 6/17/2020
Attachments: 2020-06-17_Executive_Committee_Meeting_Summary vFinal.docx

From: Melencio, Chei	yl (FNIH) [T] <	(b) (6)	On Behalf Of W	(T) (T)			
Sent: Monday, June 2	2, 2020 2:44 PM						
To: Collins, Francis (N	IH/OD) [E] <	(b) (6)	Disbrow, Gary (OS	S/ASPR/BARDA) <	(b) (6)		
Dolsten, Mikael <	(b) (6)	Fauci, A	nthony (NIH/NIAIE	(b) [E] <	(6) Gibbons, Gary		
(NIH/NHLBI) [E] <	(b) (6)	Marks, Peter	(FDA/CBER) <	(b) (6)	Pao, William		
< (b) (6)	Plump, Andı	ew <	(b) (6)	Stoffels, Paul <	(b) (6)		
Woodcock, Janet (FD:	A/CDER) <	(b) (6)	Colvis, Ch	ristine (NIH/NCAT	S) [E]		
< (b) (6)	Desrosiers, I	Betsy <	(b) (6)	Hughes,	Eric		
< (b) (6)	Jansen, Ka	athrin <	(b) (6)	Kurilla, Michae	I (NIH/NCATS) [E]		
< (b) (6)					[E] < (b) (6)		
Young, John < (b) (6) Freire, Maria (FNIH) [T] < (b) (6)							
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Alvarez, Rosa < (b) (6) Anderson, Margaret							
< (b) (6)			1 7 7 7		4 - 7 -		
					Menetski, Joseph (FNIH)		
[T] < (b) (6)			4		7 7		
Tolman, Brett <							
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(NIH/NIAID) [E] <	4 5 4 5				7 7 7 7		
) Protasiewicz,		
Ann < (b)	(6) Ri						
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< (b) (6)					Burklow, John (NIH/OD) [E]		
	Culp, Michelle						
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< (b) (6)			7 7 7 8	Parker, Ashley			
					etz, Carrie (NIH/OD) [E]		
					Carver, Trea (NIH) [C]		
< (b) (6)					s, Enrique (NIH/NCATS) [E]		
	Melencio, Che			Sepulveda, Do	orina (FNIH) [T]		
	Simon, Dina (N		4 + 4 +				
Subject: Notes from our ACTIV Executive Committee call on 6/17/2020							

Dear ACTIV Executive Committee members and meeting attendees:

Please find attached the complete meeting notes from our June 17 teleconference. Action items were previously distributed on June 18. Please let me know any questions or comments.

Regards, David Wholley

David Wholley

Senior Vice President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 2/25/2021 5:54:47 PM Levy, Ell ot [Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Gottesdiener, Keith [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Reapients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Patel, Naimish Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Carl . Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Culp, Michelfe (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

From:

Sent:

To:

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Phillips, L Revell CIV DTRA RD (USA) [Petrovick, Martha - 0449 - MITLL [(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Larry Tsai Wung, Peter K (b) (6) (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary [Butcher, Tina (b) (6) (b) (6) Demarcus (Melencio, Cheryl (FNIH) [T] (b) (6) Macone, Erin [(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijpl; Dana Carluccio (b) (6) Rose Li Central Account (b) (6) Lucas Smalldon Mollica, Linda /US (b) (6) (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa); Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYOIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Hoots, W Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a633636466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Lerner, Andrea (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=532S4f4fb04e4bcbabe37940b4b41887-fennellyam); Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya) **ACTIV Therapeutics-Clinical Working Group** (b) (6)

Subject: Attachments: ACTIV_TX-Clinical WG Meeting_20210225_v1.pdf Location: https://fnih.zoom.us/

Start: 2/25/2021 6:00:00 PM 2/25/2021 7:00:00 PM End:

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Required Attendees:

Levy, Ell ot; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER), Draghia-Akli, Ruxandra, Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T], Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLB) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees:

Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Centra Account; Lucas Smaldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, H lary (NIH/NIAID) [E]; Chen, Helen Q.; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NIAID) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Lemer, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting. See you in a few minutes.

Thanks, Stacey

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Alvarez, Rosa Maria [(b) (6) 7/8/2020 1:13:47 PM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NiH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e3Sab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea}; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams); Rao, Srinivas (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria); Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf); Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc); Desros ers, Betsy Hughes, Enc [(b) (6) (b) (6) Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla); Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh}; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth Tolman, Brett [Wachtel, Jonathan (b) (6) (b) (6) (b) (6) Prabhavathi Fernandes [(b) (6) Diamond, Michael [Rose Li (b) (6)

Dana Carluccio [

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Lagos, Enrique (NIH/NCATS)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski [Baric, Toni C (b) (6) (b)(6)Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]

Subject:

RE: ACTIV Preclinical full working group

Hi all, Please see below for today's agenda. Looking forward to our discussion at 10am.

Agenda Topic	Duration	Facilitator
Debrief from Leadership Meeting	5 mins	John Young
Discuss approach for preclinical development of combination therapies	15 mins	Christine Colvis
Debrief on NHP prioritization strategy updates	10 mins	Jim Anderson, Joe Menetski
Discuss potential plan for genotypic monitoring	10 mins	Tomas Cihlar, Marco Salemi
Sub Group Updates	15 mins	Sub Group Leads
Align on action items and next steps	5 mins	Joe Menetski Rosa Alvarez

Best regards, Joe and Rosa ----Original Appointment----From: Menetski, Joseph (FNIH) [T] < (b) (6) Sent: Tuesday, April 14, 2020 6:44 PM To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) Baric, Ralph; Ottinger, Elizabeth (NIH/NCATS (b) (6) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

Parker, Ashley (NIH/OD) [E]; Collins, Francis (b) (6) (b) (6) (b) (6) (NIH/OD) [E]; (b)(6)Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/N AID) [E], Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski, Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

Subject: ACTIV Preclinical full working group

When: Wednesday, July 8, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/27/2020 1:20:05 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith Hughes, Eric **Judy Currier** (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-iscurrier.m]; LaVange, Lisa Levy, Elliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Patel, Naimish []; Peppercom, Amanda (b) (6) (b) (6) Poole, Mike [Proschan, Michael (NIH/NIAID) (b) (6) (b) (6) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter,Stein); Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli]; Amanda Peppercorn Garner, Carl (b) (6) . Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw); Burgess, Timothy Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwainr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc), Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda] Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboiset]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis); Desrosiers, Betsy Jansen, Kathrin]; Kim, Elizabeth (b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject:

COVID-19 Status Reports and Dashboards from VA and UC System

Attachments: Copy of DailyReport 20200522.xlsx; UC Report 5-22-20 pdf

Dear ACTIV TX-Clinical Working Group,

Please find attached some initial RWD that the FDA team has been kind enough to give us access to and will update for our group each week if we would find it useful.

Please let me know if either our Agent Prioritization Subgroup or the Master Protocol Subgroup would find this data useful as we are prioritizing agents and planning trials. If so, I will work with Peter Stein to ensure our group gets the updated information at the proper cadence.

Please do not share beyond the ACTIV group at this time.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer

Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Stein, Peter < (b) (6)

Sent: Monday, May 25, 2020 6:59 PM

To: Adam, Stacey (FNIH) [T] < (b) (6)

Subject: reports

Stacey,

Amy Abernathy is coordinating a group pulling in RWD from a number of sources – with daily reports from the VA and UC system. She has permission to have these shared with the ACTIV group – so I've attached reports from last week, and if useful, we can have these at whatever frequency we prefer.

Regards, Peter

Peter P. Stein, MD
Director, Office of New Drugs, CDER/FDA

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user706e5647]; Kim,

From:

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Elizabeth [btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan Prabhavathi Fernandes [Diamond, Michael [Rose Li (b) (6) (b)(6)Dana Carluccio Lagos, Enrique (NIH/NCATS) (b) (6) (b)(6)[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D Dave Frankowski [Baric, Toni C (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh); Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=usere3ed7188]; Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen [(b) (6) (b)(6)**ACTIV Preclinical full working group** https://fnih.zoom. (b) (6) 9/23/2020 2:30:00 PM 9/23/2020 3:30:00 PM Show Time As: Tentative Recurrence: Weekly every Wednesday from 10:00 AM to 11:00 AM Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) kara. (b) (6) (b)(6)(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b)(6).gov; (b) (6) (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E); (b) (6) ; Adams, Peter (OS/ASPR/BARDA), Rao, Srinivas, Qashu, Felicia (NIH/OD) [E]; (b) (6) Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturien, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michae (NIH/NCATS) [E]; Lowy, Doug as (NCI) Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kım, Elizabeth; Tolman, Brett; Wachtei, Jonathan; Prabhavathi Fernandes; Dramond, Michael; Rose Li, Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, N na; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b)(6)

Changing time for this meeting at the request of the cochair.

Subject:

Location:

Required

Optional Attendees:

Attendees:

Start:

End:

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Join Zoom Meeting
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Find your local number: https://fnih.zoom.
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Start: 2/4/2021 6:00:00 PM End: 2/4/2021 7:00:00 PM

Recurrence: (none)

Required Attendees:

To:

CC:

Burgess, Timothy; Adam, Stacey (FNiH) [T]; Bozzette, Sam (NIH/NCATS) [E], Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra, Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth, LaVange, Lisa, Levy, Ell ot; Mellors, John; Menon, Sandeep; Parker, Ashiey (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda

Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E], Goff, David (NIH/NHLBI) [E] Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E], Culp, Michelle (b) (6) (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E] DTRA RD (USA); Petrovick, Martha -(b) (6) 0449 - MITLL; Sizemore, Christine (NIH/FIC) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)

Optional Attendees:

(b) (6) Feltquate, David; Larry Tsai
Chen, Helen Q., Sorosa, Alex David; Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young,
John; Biggs, Mary, Butcher, Tina, Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski,
Joseph (FNIH) [T], Dana Carluccio; Rose Li Central Account; Lucas Smalldon; (b) (6) Mol ica,
Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary
(NIH/NIAID) [E]; Chen, Helen; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E];
Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; (b) (6) DTRA J9 (USA); (b) (6)

USARMY DOD JPEO CBRND (USA), Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne
(NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; LEVINE, MICHAEL; Armstrong, Linda

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Attachments: ACTIV TX-Clinical_Working Group Meeting Guide 20201029.pdf

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Show Time As: Tentative

Recurrence: (none)

every Thursday from 1:00 PM to 2:00 PM

Required Attendees:

Draghia-Ak i, Ruxandra; Eisner, Mark, Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Ell ot; Mellors, John, Menon, Sandeep; Parker, Ashiey (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E], Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, Li Revell CIV DTRA RD (USA); Petrovick, Martha – 0449 - MiTLL; (b) (6)

Sizemore, Christine (NIH/FIC) [E]; Bozzette, Sam (NIH/NCATS) [E], Butterton, Joan; De Claro, R. Angelo (FDA/CDER);

Optional Attendees: Gonzalez, Nina; Colvis, Christine (NIH/NCATS) [E], Desrosiers, Betsy; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary, Butcher, Tina; Demarcus, Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Dana Carluccio, Rose Li Central Account, Margaret Anderson; Lucas Smalldon, Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzeiski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia, Walker, Paula (NIH/NINDS) [E]; Bethany Stokes; Sorosa, Alex David

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's meeting in 20 minutes. Thanks,

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Stacey

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Jonathan Prabhavathi Fernandes [(b) (6) (b) (6) Rose Li Dana Carluccio 1 Lagos, Enrique (NIH/NCATS) (b)(6)(b) (6) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; .onson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Dave Frankowski Baric, Toni C [(b) (6) (b)(6)Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NiH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-fiorencewc]; Stratton, Benjamin Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon oh]; Rodriguez Robin D [rmdaigle@tulane_edu]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes); Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Caroline Sferrazza (b) (6) Diamond, Michael (b) (6) **ACTIV Preclinical full working group** https://fnih.zoom.us/ (b)(6)7/29/2020 2:00:00 PM 7/29/2020 3:00:00 PM Recurrence: (none) Adams, Peter (OS/ASPR/BARDA); Collins, Francis (NIH/OD) (b)(6)(b) (6) Attendees: [E]; (b) (6) (b)(6)Hild, Sheri (NIH/OD) [E]; (b) (6) Parker, Ashley (b) (6) (b) (6) (b) (6) (b)(6)(NIH/OD) [E]; Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, (b) (6) Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturien, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Diamond, Michael; Nancy Haigwood, Rodriguez, Robin D; Austin, Christopher (NIH/NCATS) [E]; Hughes, Eric, Attendees: Anderson, James (NIH/OD) [E]; Caroline Sferrazza; Wholley, David (FNIH) [T]; Meiencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T], Santos, Michael (FNIH) [T], Adam, Stacey (FNIH) [T]; James, Stephanie (FN H) [T]; Alvarez, Rosa Maria, Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Cartuccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E];

Florence, Clint (NIH/NIAID) [E]; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 12/12/2020 12:48:32 PM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark [(b) (6) Gottesdiener, Keith (b)(6)Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [(b) (6) Levy, Eliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Carl : Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Culp, Michelfe (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

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Summary of the ACTIV Therapeutics-Cinical Working Group Meeting

CC:

Subject:

GADB0000001816-2516937

Attachments: 2020-12-10 TX-Clinical WG Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Please find attached the summary of our meeting on Thursday. If you have any additions or amendments, please be sure to send them my way.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
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[/o=ExchangeLabs/ou=Exchange Administrative Group]
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group]
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                                 Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group]
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                           Paul Gillard [
                                                            François P Roman [
                                              (b) (6)
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Subject: Agenda and notes for ACTIV Vaccines Working Group meetings

Attachments: 2021-02-18 Vaccines Working Group meeting Summary Notes.docx; ACTIV TRACE Slides v5.pptx

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The topic for this meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from Thursday's meeting are attached. We sincerely thank Penny and Alex for their presentations on the implications of the 501Y.V2 variant for natural and vaccine-derived immunity and the cross-neutralization of responses to 501Y.V2 infections against ancestral virus. In addition, Joe Menetski's slides on the new ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) Working Group are attached, and anyone interested in more information or participating should feel free to reach out to Joe (b) (6)

We welcome additional comments and questions any time.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, February 17, 2021 6.25 PM

Subject: Agendas and notes for ACTIV Vaccines Working Group meetings

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Thursday) at 2pm ET / 11am PT / 8pm CET.

The topic for this meeting will be antibody immunity to 501Y.V2 through vaccination and infection, with presentations from Penny Moore (South Africa's National Institute of Communicable Diseases) and Alex Sigal (Africa Health Research Institute).

Our third meeting on the topic of viral variants will be Monday, 22 Feb. The agenda for that meeting is a discussion of what information we need to acquire before adding vaccination against a variant strain to a country/region's vaccination strategy. Doug will initiate the conversation then invite perspectives from the participants.

Notes from our first meeting on this topic are attached, with appreciation again to Trevor Bedford and Jesse Bloom and for the many contributions of meeting participants.

Finally, we wanted to provide an update on the concept of a trial to assess the impact of vaccination on infection transmission and viral load, which we discussed in meetings in late 2020. A modified version of the protocol that we discussed has been supported to move forward. The trial plans to enroll 12,000 students including at HBCUs, split between immediate-vaccination and delayed-vaccination arms (substituting delayed vaccination for placebo eased regulatory requirements), with daily viral sampling and contact tracing of infections as possible.

As always, please reach out with any questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science: Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Thursday, February 11, 2021 2.59 PM

Subject: Slides from today's ACTIV Vaccines Working Group meeting

Hi all,

Thanks again to Trevor and Jesse for their insightful presentations and to everyone who participated in the meeting. Trevor and Jesse have kindly made their slides available at:

- https://bedford.co/talks/sars.cov_2_molecular-evolution-activ/#/ (advance with space-bar or arrows)
- https://slides.com/jbloom/sars-cov-2_activ

We will be following up with meeting notes, and will send an invite for our next meeting as soon as we can.

Best regards, Brett and Mike

Viichael Santos, PhD

Associate Vice President, Science - Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, February 9, 2021 5:54 PM

Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Thurs, 11 Feb)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, Thursday at 11:30am ET / 8:30am PT / 5:30pm CET Please note that this meeting is scheduled for 75 min to allow for more discussion.

The topic for this meeting (and planned subsequent meetings) is the evolution of viral variants and the implications for vaccines. For our meeting Thursday, Jesse Bloom and Trevor Bedford of Fred Hutch will join us to present on the genetics of the epidemic and predictive analytics, followed by discussion during which we welcome participants to share the activities that their organizations are undertaking in response.

As always, please reach out with any questions or suggestions.

Best regards, Brett and Mike

Wichael Santos, PhD

Associate Vice President, Science : Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Sunday, December 13, 2020 7:11 PM

Subject: Agenda for the next ACTIV Vaccines Working Group meeting (Monday, 14 Dec)

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Monday) at 12pm ET / 9am PT / 6pm CET.

The main agenda item for tomorrow is discussion of potential approaches to evaluate the impact of vaccines on transmission. This topic was presented and discussed at the 18 Nov meeting of the Vaccines CI nical Trials Sub-Group If you were unable to join that meeting (or to refresh your memory), the notes with presentation materials embedded are attached.

If we have additional time after that discussion, we may discuss Working Group member perspectives on the other topics that have been discussed recently in the Clinical Trials Sub-Group: the potential for blinded cross-over within studies (30 Nov, notes attached) and evaluating vaccines in immunocompromised populations (10 Dec, notes still to come).

If you cannot join the meeting but would like to provide input on any of the topics above, please send it to us prior to Wednesday, when Doug will be reporting on behalf of the group to the ACTIV Leadership Team.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President. Science: Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, November 18, 2020 7:13 PM

Subject: Notes from the ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

With apologies for the delay, attached are notes and the single slide from last week's Vaccines Working Group meeting.

After the meeting, the Working Group and Sub-Group leadership aligned on the immediate priorities for discussion. Those begin today with the Vaccine Clinical Trial Sub-Group's meeting on evaluating the impact of vaccines on transmission. Topics prioritized for subsequent discussions include potential blinded cross-over for ongoing phase 3 trials, preparing for the possibility of vaccine efficacy varying by platform/product, and evaluating vaccines in immunocompromised populations. Invitations for meetings on those topics will be sent soon.

As always, we welcome addition comments and questions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, November 10, 2020 1:33 PM

Subject: Agenda for tomorrow's ACTIV Vaccines Working Group meeting

Dear Vaccines Working Group members,

We're looking forward to our next meeting, tomorrow (Wednesday) at 1pm ET / 10am PT / 7pm CET. We scheduled this meeting last week without knowledge of yesterday's exciting announcement, and are delighted to be re-convening this group at such an auspicious time.

As we described below, the agenda for tomorrow is an open discussion of the priorities for vaccines in addition to the licensure studies that the Vaccines Working Group or the Clinical Trials Sub-Group should consider. Some members of the group have already proposed a few ideas, and all members of the group are invited to make additional suggestions and weigh in on the potential opportunities. After the meeting we will prioritize next steps.

If you cannot attend tomorrow's meeting, as always please feel free to submit ideas in advance that we can share on your behalf or send feedback on the notes afterwards.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Friday, November 6, 2020 1:01 PM

Subject: Next ACTIV Vaccines Working Group meeting. Weds, 11 Nov

Dear Vaccines Working Group members,

As you may recall from the summer, we agreed to stop regular meetings of the Vaccines Working Group and reconvene as needed. Our next meeting will be Wednesday, 11 Nov, at 1pm ET (10am PT / 7pm CET).

We've been requested by ACTIV leadership to have a discussion about the priorities for vaccines in addition to the licensure studies. The Vaccines Clinical Trials Sub-Group has had previous meetings on the topics of evaluation in pregnant and pediatric populations, and is planning upcoming conversations about studying impact on transmission and evaluation in immunocompromised populations, as well as a discussion of the potential application of expanded access protocols.

At our next Working Group meeting, we would appreciate input on those and other potential priorities for discussion within the group. We are looking forward to your thoughts, and as always appreciate any questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

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Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] 6/11/2020 7:38:53 PM Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Admin strative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa); (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai], Ottinger, Elizabeth (NiH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, .udith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melenc o, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christ ne (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Enc [(b) (6) (b) (6) Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh); Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; .ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria Kim, Elizabeth Tolman, Brett [Wachtel, (b) (6) Jonathan Prabhavathi Fernandes [Diamond, Michael (b) (6) (b) (6)

Dana Carluccio

Rose Li

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Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D Dave Frankowski Baric, Toni C (b) (6) (b)(6)Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd); Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel) Subject: ACTIV Preclinical full working group Location: https://fnih.zoom. (b) (6) Start: 6/24/2020 2:00:00 PM End: 6/24/2020 3:00:00 PM Show Time As: Tentative Recurrence: Weekly every Wednesday from 10:00 AM to 11:00 AM Required Punturieri, Antonello (NIH/NHLBI) [E], Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Attendees: (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]; (b)(6)(b)(6)(b) (6) (b) (6) (b)(6)(b)(6)(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b)(6)Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Adams, Peter (b)(6)(OS/ASPR/BARDA); Rao, Smrivas; Qashu, Felicia (NtH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Charette, Marc (NIH/NHLBI) [E] Optional Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine Attendees: (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michae (NIH/NCATS) [E]; Lowy, Doug as (NCI), Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li, Dana Carluccio, Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E], Gonzalez, N na, Simon, Dina (NIH/OD) [C], Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodinguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E], Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E] Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fn:h.zoom. (b) (6) Meet ng ID: (b) (6) Password: (b) (6)

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From: Melencio, Chery! (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOCI Sent: 1/12/2021 9:53:35 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] ; Carter, Kara [Cavaleri, Marco (b) (6) (b) (6) Cihlar, Tomas]; Collins, Francis (NIH/OD) [E] (b) (6) (b) (6) Corey, Larry Culp, Michelle (NIH/OD) [E] [(b) (6) (b) (6) Victoria Davey [Disbrow, Gary (OS/ASPR/BARDA) | Dolsten, Mikael (b) (6) (b) (6) Erbelding, Emily (NIH/NIAID) [E] [Erck, Stan (b)(6)(b)(6)Gadbois, Ellen (NIH/OD) [E] []; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) (b) (6) Hudson, Thomas James, Stephanie (FNIH) [T] (b)(6)(b) (6) Johnson, Robert (OS/ASPR/BARDA) | Kramer, Lynn (b)(6)(b) (6)]; Lane, Cliff (NIH/NIAID) [E] [Mascola, John (NIH/VRC) [E] (b) (6) (b) (6) (b)(6)Meeker, David (b)(6)Menetski, Joseph (FNIH) [T] Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b) (6) Pandya, Hitesh (b)(6)Pao, William Parker, Ashley (NIH/OD) [E] (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Perlmutter, Roger (b) (6) Plenge, Robert [(b) (6) Plump, Andy Reese, David [Rouse, Doris [(b) (6) Santos, Michael (b) (6) (b) (6) (FNIH) [T] [Skovronsky, Daniel [Stein, Peter (FDA/CDER) (b)(6)Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] (b)(6)(b) (6) Talley, Michael [Tsai, John (b) (6) (b) (6) (b) (6) Vessey, Wholley, David (FNIH) [T] [Rupert I (b) (6) Virgin, Skip [(b)(6)(b)(6)Woodcock, Janet (FDA/OC) [(b) (6) Young, John (b)(6)Anderson, James (NIH/OD) [E] Burklow, John (NIH/OD) [E] [(b)(6)Carluccio, Dana (b) (6) Castillejos, Carlos [**FNIH Central Account** (b) (6) (b) (6) Lumsden, Joanne]; Hallett, Adrienne (NIH/OD) [E] [(b) (6) (b) (6) (NIH/NCATS) [C] [(b) (6)]; Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [Colvis, Christine (NIH/NCATS) [E] [Descosiers. (b) (6) (b) (6) Betsy []: Eric Hughes [eric. Jansen, Kathrin (b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [Lowy, Douglas (NCI) (b) (6) (b) (6) Read, Sarah (NIH/NIAID) [E] [Meltzer, Abbey (FNIH) [T] (b) (6) (b) (6) Adam, Stacey (FNIH) [T] [(b) (6) (b) (6) Margaret Anderson (b) (6) Appell, Evan (Chen, Helen [(b) (6) (b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina (b) (6) Hawk, Harrison]; Mendelson, Jesse [Nasr, Hana ((b) (6) Sorosa. (b)(6)(b) (6) Alex [Stratton, Benjamin [btolman | (b) (6) (b) (6) (b) (6) Wachtel, Jonathan [Embry, Alan (NIH/NIAID) [E] (Venkayya, Rajeev (b) (6) (b) (6) Bancel, Stephane [(b) (6) (b) (6) (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci); Lepore, John Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda], Pangalos, Mene Paul, Steve (b) (6) Ramoni, Rachel [(b) (6) Reed, John [(b)(6)CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [E] Burrus-Shaw, Cyndi (NIH/OD) [E] [Carver, Trea (NIH) [C] (b) (6) (b) (6) Coan, Amanda | (b) (6) Caulfied, Anita (b) (6) (b) (6) Conrad, Patricia (NIH/NIAID) [E] [Dimishkov, Roxanne (NIH/NHLBI) [C] (b)(6)); Edl, Susan [Fuhrer, Nicole (b)(6)(b) (6) (b) (6) Hoban, Michelle [Hoffstetter, Renata (FNIH) [T] Giorgi, Sara ((b) (6) (b) (6) Iberdemaj, Vaide [Jenkins, Christine S. (b) (6) (b)(6)Lagos, Enrique (NIH/NCATS) [E] [(b) (6) (b) (6) Lever, Susan (b) (6) Magbie-Robinson, Kım (NIH/OD) [C] [kım. (b) (6) Martin, Melisa [McManus, Ayanna (NIH/OD) [E] []; Minnich, Beth (b) (6)

(b) (6)	Perala, Mie [(b) (6)	Protasiewicz, Ann	
(b) (6)	Riccobene, Kir	m (b) (6)	Riggin, Mary [(b) (6)
Ripley, Nadege [(b) (6)	Schuster, Donna	(b) (6)	Sepulveda,
Dorina (FNIH) [T] [(b) (6) Simo	on, Dina (NIH/OD) [C]	(b) (6)	Suhana, Tina (NIH/VRC)
[E] (b) (6)	.gov]; Thomas, Ashley (FDA/CDER) [(b) (6)	Wood, Gretchen (NIH/OI
[E] [(b) (6)	Hughes, Karen (NIH,	/OD) [E] (b)	(6) ; Togash	i, Mieko (NIH/NG) [E]
(b) (6)]; Underwood, N	ancy [(1	b) (6) Z	ottoli, Jessica
(b) (6)	Regan, Donna M	(b) (6)	Vessey, Rup	ert
(b) (6)]; Burke, Leslie [(b) (6)	John Lepore [(b) (6)
Lowy, Douglas (NIH/N		Grant, Sarah [(b) (6)	Pruitt, Kim
(NIH/NLM/NCBI) [E] [(b) (6)	Sherry, Steve (NIH/	NLM/NCBI) [E] [(b) (6) Bell,
Julie (b) (6	5)			

Subject: ACTIV Leadership Team Call #14

Attachments: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, March 18, 2021

Location: https://fnih.zoom.us/ (b) (6)

Start: 3/18/2021 2:30:00 PM End: 3/18/2021 4:00:00 PM

Show Time As: Busy

Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA), Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John, Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E], Talley, Michael; Tsai, John, Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos, FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric, Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E], Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Meltzer, Abbey (FNIH) [T]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison, Mendelson, Jesse; Nasr, Hana; Sorosa, Alex, Stratton, Ben; Tolman, Brett; Wachte, Jonathan; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; (b) (6)

Optional Attendees:

Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NiH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole, Giorgi, Sara, Hoban, Michelle; Hoffstetter, Renata (FNIH) [T], Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly, Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa, McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary, Ripley, Nadege, Schuster, Donna; Sepulveda, Dorina (FNIH) [T], Simon, Dina (NIH/OD) [C], Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) (E]; Hughes, Karen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy, Zottoli, Jessica, Regan, Donna M; Vessey, Rupert; Burke, Leslie; John Lepore; Lowy, Douglas (NIH/NCI) [E]; Grant, Sarah; Pruitt, Kim (NIH/NLM/NCBI) [E]; Sherry, Steve (NIH/NLM/NCBI) [E]

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 1/16/2021 12:44:39 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [(b) (6) Levy, Eliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep [Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmrl; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Carl : Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | Petrovick, Martha - 0449 - MITLL [(b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Jansen, Kathrin (b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary Butcher, Tina [(b) (6) Demarcus i Melencio, Cheryl (FNIH) [T] (b) (6) Macone, Erin [(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Dana Carluccio Rose Li Central Account Lucas Smalldon (b) (6) (b) (6) (b) (6) (b) (6) Mollica, Linda /US (b) (6) Qashu, Felic a (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Wung, Peter /US Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a633636466793cff9145b09d91b-Contact_f12]; Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm] Summary of the ACTIV Therapeutics-Clinical Working Group

Subject:

CC:

Attachments: 2021-01-14_TX-Clinical_WG_Meeting_Summary.pdf

Dear ACTIV TX-Clinical WG,

Thank you all for a very good discussion yesterday on the potential path forward for testing additional widely available agents. Please find attached the summary of the meeting if you have any additions or amendments, please let me know.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

Foundation for the National Institutes of Health

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Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes), Judy Currier
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                       Alvarez, Rosa [
                                                             Stratton, Benjamin (
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(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group]
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                   Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI8OHF23SPDLT)/cn=Rec pients/cn=user3c2f486d];
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[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                 Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange
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                           Biggs, Mary [
                                                              Butcher, Tina
                                               (b) (6)
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Demarcus [
                                    Macone, Erin
                                                                     Melencio, Cheryl (FNIH) [T]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647); Dana Carluccio
                                    Rose Li Central Account
                                                                                     Lucas Smalldon
               (b) (6)
                                     Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group]
               (b) (6)
(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188];
                                                                               Mollica, Linda /US
                                                             (b) (6)
                          Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda1, Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user34aa917e]; Wung, Peter /US [Hoots, W. Keith (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave) CIV DTRA J9 (USA) [Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Elsaid, Olivia (/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Bethany Stokes (b) (6)

Attachments: ACTIV TX-Clinical_Working Group Meeting Guide 20201001 vF.pdf

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 10/1/2020 5:00:00 PM

 End:
 10/1/2020 6:00:00 PM

Show Time As: Tentative

Recurrence: (none)

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Levy, Ell ot; Jacqueline Kirchner; Garner, Carl; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra, Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah, Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Higgs, Elizabeth (NIH/NIAIO) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]

(b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]

Optional Attendees: Merritt, Gabriella Marie, Margaret Anderson, Gonzalez, Nina; Kunlla, Michael (NIH/NCATS) [E];

(b) (6) Stock, Thomas (HHS/IOS); Freire, Maria (FNIH) [T], Desrosiers, Betsy; Colvis, Christine (NIH/NCATS) [E], Jansen, Kathrin, Lowy, Douglas (NCI); Young, John; Biggs, Mary, Butcher, Tina, Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T], Salathin, Carla, Tountas, Karen (FNIH) [T], Menetski, Joseph (FNIH) [T]; James, Stephanie (FN H) [T], Wachtei, Jonathan, Tolman, Brett; Alvarez, Rosa; Dana Carluccio; Rose Li Central Account, Lucas Smalldon; Stratton, Benjamin; (b) (6) Molica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzejski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Elsaid, Olivia; Walker, Paula (NIH/NINDS) [E]; Bethany Stokes

Dear ACTIV TX-Clinical WG,

Please find attached the slides for today's presentation.

Thanks, Stacey

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 10/24/2020 3:04:02 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49Sc3ee2Sca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [(b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith (b)(6)Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [(b) (6) Levy, Eliot [(b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Patel, Naimish Peppercorn, Amanda [(b) (6) (b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli); Amanda Peppercorn Garner, Carl : Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg); Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (N H/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef); Culp, Michelfe (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

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Attachments: 2020-10-22_TX-Clinical_WG_Meeting_Summary.pdf

Subject:

CC:

Dear ACTIV TX-Clinical WG Members,

Please find a summary of the meeting yesterday. Thank you all for a great discussion. If you have any additions or amendments, please let me know!

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct

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Chen, Helen Q. [(b) (6) 9/10/2020 4:44:39 PM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [Eisner, Mark [(b) (6) Gottesd ener, Keith (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa [Levy, Eliot Mellors, John W (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Rec pients/cn=user257cb364]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Menon, Sandeep [(b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish (b) (6) Peppercorn, Amanda [(b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva Colli]; Amanda Peppercorn (b) (6) Garner, Carl (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw); Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla); Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr); Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NiH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Jacqueline Kirchner

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                                                   Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                                                                             Mollica, Linda /US
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              RE: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: ACTIV_TX-Clinical_Working Group Meeting Guide 20200910.pdf
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Dear ACTIV TX-Clinical Working Group Members,

Subject:

CC:

Please find attached the presentation for our meeting at 1pm ET. Looking forward to speaking with you all soon!

warm regards, He] en ----Original Appointment----From: Adam, Stacey (FNIH) [T] < (b) Sent: Wednesday, June 17, 2020 8:48 AM To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth, LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish, Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Reveil CIV DTRA RD (USA); Peteovick Martha - 0449 - MITL: (b)(6) Sizemore, Christine (NIH/FIC) [E] Petrovick, Martha - 0449 - MITL; (b)(6) Sizemore, Christine (NIH/FIC) [E]

Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS)

[E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio,

Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James,

Stephanie (FNIH) [T]; wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana

Carluccio: Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;

(b)(6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI)

[E]; Rubin, Daniel B. (FDA/CDER): Marston, Hilary (NIH/NIATD) [F1: Chen, Helen Qui Mung, Peter, Alson [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]: Groesch. Mary (NIH/NHLBI) [E]; Shipp. Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; (b) (6) CIV DTRA J9 (USA); (b) (6) USARMY DOD JPEO Andrei (NIH/NHLBI) [E]; (b)(6) CIV DTRA CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia Subject: ACTIV Therapeutics-Clinical Working Group Meeting when: Thursday, September 10, 2020 1:00 PM 2:00 PM (UTC 05:00) Eastern Time (US & Canada). where: https://fnih.zoom. (b)(6) Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fmih.zoom. (b)(6)Meeting ID: Password: (b) (6) One fan mohile (b) (6) US (Germantown) US (Chicago) Dial by vour location (b)(6) US (Germantown) US (Chicago) US (New York) US (Tacoma) US (Houston) US (San Jose) US (San Jose) (b)(6)Meeting ID: Password: (b)(6)
Find your local number: https://fnih.zoom.us (b)(6) This message (including any attachments) contains contidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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(b) (6)	Kım, Elizabeth [(b) (6)	Tolman, Brett [(b) (6)	Wacntel,
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From: Sent: To:

	Jonathan	(b) (6)	Prabhavathi Fernandes	(b) (6)) Rose Li				
	[(b) (6)	Dana Carluccio [(b) (6)]; Lagos, Enrique (NIH/NCATS)				
	[E] [/o=Exc	[E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF	23SPDLT)/cn=Re	cipients/cn=ae9041ab27204d8	3b06752f67a44b0d1-	lagoses]; .onson, Samantha				
	(NIH/NCAT	(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina							
	[/o=Exchar	ngeLabs/ou=Exch	ange Administrative Group (FY	DIBOHF23SPDLT)/cn=	Rec pients/cn=user3c2f486d];				
	Simon, Diri	a (NIH/OD) [C] [/	o=ExchangeLabs/ou=Exchange	Administrative Group					
	(FYDIBOHF	23SPDLT)/cn=Re	cipients/cn=e02345fa5d1d4d7e	eaf4e0f3da58bc1ac-si	mondm]; Burrus-Shaw, Cyndi				
	(NIH/OD) [(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF	(FYDIBOHF23SPDLT)/cn=Recipients/cn=Sbbac95b1f6e4514a299b318030c31f6-shawcy); Rodriguez, Robin D							
	i d) (6) Da	ve Frankowski [(b) (6)	Baric, Toni C				
	[(b) (6)	Lowy, Douglas (NIH/NCI		os/ou=Exchange Administrative				
	Group (FYI	Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood							
	[/o=ExchangeLabs/ou=Exchange Administrative Group								
	(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh); Stratton, Benjamin								
		(b) (6)	Gadbois, Ellen (NIH/OD) [E] [/	o=ExchangeLabs/ou=	Exchange Administrative Group				
	(FYDIBOHF	(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James							
	(NIH/OD) [(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group							
	(FYDIBOHF	(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm];							
		(b) (6)	Diamond, Michael [(b) (6)					
Subject:	Re: ACTIV	Preclinical full wo	rking group						

Dear Tom,

we also have been monitoring mutations in CoV-2 isolates with some of our in house tools and we are certainly very interested. We have algorithms to test selection pressure, as well as collaborations with structural biology groups that have been mapping mutations on 3D structures. It would be great if we could come up with a comprehensive tool capable of implementing all these different analyses.

Concerning, specifically, the D614G mutations, our statistical analyses on its association to higher mortality do not seem to show a clear effect, although the analyses are certainly affected by sampling bias and the fact that sequences currently available in databases are not sufficiently annotated (e.g., for most of them, we do not have clinical metadata on the infected patients).

As of right now, most mutations seem to accumulate through random genetic drift followed by founder effects, but of course the situation could quickly change, as soon as selective pressure exerted by drugs will start acting on the virus. Having tools capable of effectively monitoring mutation frequencies in populations under different selective constrains will certainly be crucial to detect and monitor possible emergence of drugresistant or more virulent strains.

Best,

Marco

Marco Salemi, Ph.D. Professor in Experimental Pathology Holloway and McClamma Chair Department of Pathology, Immunology and Laboratory Medicine University of Florida College of Medicine

Emerging Pathogens Institute P.O. Box 100009 Ga nesville, FL 32610-3633, U.S.A. Tel/Fax +(______ From: Rappaport, Jay < (b) (6) Sent: Wednesday, July 1, 2020 2:21 PM To: Tomas Cihlar; Punturieri, Antonello (NIH/NHLBI) [E]; Florence, Clint (NIH/NIAID) [E]; Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6) (b) (6) (b) (6) (b)(6)Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Pitt, (b) (6) Margaret L CIV USARMY MEDCOM USAMRIID (USA), Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6) Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; (b) (6) Melencio, Chery (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E], Nancy Haigwood; Stratton, Benjamin, Gadbois, Ellen (NIH/OD) [E], Anderson, James (NIH/OD) [E]; Diamond, Michael Cc: Salemi, Marco Subject: Re: ACTIV Preclinical full working group {Externa. Email} Thomas, This is a very interesting question. Marco Salemi has a very large collection of CoV-2 viral sequences globally and is an expert in viral evolution. Perhaps he can comment. Best, Jav. Jay Rappaport Get Outlook for IOS From: Tomas Cihlar < (b) (6) Sent: Wednesday, July 1, 2020 1:14:09 PM To: Rappaport, Jay < Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Florence, Clint (NIH/NIAID) [E] < Menetski, Joseph (FNIH) [T] < Hila, Sheri (b) (6) (b) (6) (NIH/OD) [E] < (b) (6) (b) (6) (b) (6) (b) (6) < (b) (6) (b) (6) < (b) (6) (b) (6)

Wholley, David (FNIH) [T] < (b) (6) (b) (6) (b) (6) Austin, Christopher (N1H/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Colvis, Christine (NIH/NCATS) [E] < Desrosiers, Betsy < (b) (6) Hughes, **(b) (6)** Kurilla, Michael (NIH/NCATS) [E] (b)(6)Jansen, Kathrin < (b) (6) < Lowy, Douglas (NCI) < Read, Sarah (NIH/NIAID) [E] < (b) (6) (b) (6) (b)(6)Tountas, Karen (FNIH) [T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < Wachtel, Jonathan (b) (6) Prabhavathi Fernandes < Rose Li < (b)(6)(b)(6)< Dana Carluccio < Lagos, Enrique (NIH/NCATS) [E] (b)(6)(b)(6)Gonzalez, Nina < (b) (6) Jonson, Samantha (NIH/NCATS) [E] < (b)(6)< Simon, Dina (NIH/OD) [C] < Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) (b) (6) Rodriguez, Robin D < Dave Frankowski (b)(6)< (b) (6) Baric, Toni C < Lowy, Douglas (NIH/NCI) [E] e (b)(6)(b)(6)Nancy Haigwood < Stratton, Benjamin < (b) (6) (b)(6)(b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) Diamond, Michael < (b)(6)(b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

External Sender. Be aware of links, attachments and requests.

Dear all,

Apologies if I state something obvious that has been discussed during today ACTIV meeting as I have been simultaneously listening to the WHO COVID forum and might have missed it.

The point I want to make is about analysis of genetic changes in the CoV2 virus over time. D614G is only one example that caught peoples eye since the prevalence is so obvious now, but other changes in other proteins of the virus might be happening that could potentially be relevant for sensitivity to new drugs that we are/will be triaging. As of now there are more than 50,000 sequences available in public databases wor dwide. My question is whether there would be interest in monitoring CoV2 sequences over time with a focus on genes most relevant as antiviral targets. Gilead has built infrastructure to do this effectively, initially for nsp12 gene because of remdesivir, but we then expanded to some of the other CoV2 genes and through that we first noticed D614G as early as in mid March long before it became highly prevalent. If there is interest, I'd be happy to discuss the genotypic monitoring at one of the future calls.

Thank you,

Tomas

Tomas Cihlar, PhD Vice President, Virology Gilead Sciences, Inc. Office: (b) (6)

Email:

From: Rappaport, Jay < (b) (6)
Sent: Wednesday, July 01, 2020 8:51 AM

To: Punturieri, Antonello (NIH/NHL8I) [E] < Florence, Clint (NIH/NIAID) [E] (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Hild, Sheri (NIH/OD) [E] < (b) (6) (b) (6) (b) (6) (b) (6) (b)(6)jay_grob (b) (6) (b) (6) Baric, Ralph < (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] < Colvis. (b) (6) (b) (6)

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Christine (NIH/NCATS) [E] <
                            (b) (6)
                                         Hewitt, Judith (NIH/NIAID) [E] <
                                                                        (b) (6)
Deming, Damon (FDA/CDER) <
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Parker, Ashley (NIH/OD) [E] < (b) (6)
                                        Collins, Francis (NIH/OD) [E] (b) (6) >;
                           Adams, Peter (OS/ASPR/BARDA) < (b) (6)
          (b) (6)
                                                                        Rao, Srinivas
                      Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar
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                      Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
         (b) (6)
                     Charette, Marc (NIH/NHLBI) [E] < (b) (6)
                                                                     Fessel, Josh
     (b) (6)
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                                                                        Wholley, David
\{NIH/NHLBI\} [E] < (b) (6)
                                                        (b) (6)
(FNIH) [T] < (b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6)
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                    (b) (6) Colvis, Christine (NIH/NCATS) [E] <christine.
Cheryl (FNIH) [T] <
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Desrosiers, Betsy <
                         (b) (6) Hughes, Eric < (b) (6)
                                                                           Jansen,
                        Kurilla, Michael (NIH/NCATS) [E] (b) (6)
Kathrin < (b) (6)
                                                                          Lowv.
Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH)
[T] < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T]
               James, Stephanie (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
         (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6)
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Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6)
Rose Li < (b) (6)
                       Dana Carluccio < (b) (6)
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                      (b) (6) Jonson, Samantha (NIH/NCATS) [E]
Enrique (NIH/NCATS) [E] <
      (b) (6)
                       Gonzalez, Nina < (b) (6) Simon, Dina (NIH/OD) [C]
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                  Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
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                  Dave Frankowski <
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                                                                Baric, Toni C
                  Lowy, Douglas (NIH/NCI) [E] < (b) (6) Nancy Haigwood
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             Stratton, Benjamin < (b) (6) Gadbois, Ellen (NIH/OD) [E]
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               Anderson, James (NIH/OD) [E] <
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< (b) (6)
              (b) (6) Diamond, Michael <
Annaliesa.
                                              (b) (6)
Subject: [EXTERNAL] Re: ACTIV Preclinical full working group
Clint and Tony, thanks, important observations.
Best,
Jay
From: "Punturieri, Antonello (NIH/NHLBI) [E]" <
                                           (b) (6)
Date: Wednesday, July 1, 2020 at 10:43 AM
To: "Florence, Clint (NIH/NIAID) [E]" (b) (6)
                                               "Menetski, Joseph (FNIH) [T]"
                                          (b) (6) (b) (6)
< (b) (6)
                 "Hild, Sheri (NIH/OD) [E]" <
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                                                            "Rappaport, Jay"
<david.j. (b) (6)
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                       "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) "Hewitt, Juditn
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(NIH/NIAID) [E]" <
                    (b) (6) "Deming, Damon (FDA/CDER)" <
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        (b) (6)
                                    "Collins, Francis (NIH/OD) [E]" < (b) (6)
Ashley (NIH/OD) [E]" <
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                                                      "Adams, Peter (OS/ASPR/BARDA)"
                     <
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                                                   "Qashu, Felicia (NIH/OD) [E]"

(b) (6) USARMY N
                    "Rao, Srinivas" <
                                        (b) (6)
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                   Tomas Cihlar <
                                                         (b) (6) USARMY MEDCOM
       (b) (6)
                                       (b) (6)
USAMRIID (USA)"
                                      "Charette, Marc (NIH/NHLBI) [E]" < (b) (6)
                       (b) (6)
"Fessel, Josh (NIH/NHLBI) [E]" < (b) (6)
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                                                                            "Wholley, David
(FNIH) [T]" <
                             "Austin, Christopher (NIH/NCATS) [E]" <
                                                                       (b) (6) "Melencio.
              (b) (6)
                       (b) (6) "Colvis, Christine (NIH/NCATS) [E]" <
Cheryl (FNIH) [T]" <
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                                                "Hughes, Eric" <
"Desrosiers, Betsy" <
                            (b) (6)
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                                                                                      "Jansen,
Kathrin" <
                                                                                       "Lowy,
                                  "Kurilla, Michael (NIH/NCATS) [E]" <
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                             "Read, Sarah (NIH/NIAID) [E]" < (b) (6)
Douglas (NCI)" <
                                                                             "Tountas, Karen
                  (b) (6)
(FNIH) [T]" <
                            "Santos, Michael (FNIH) [T]" <
                                                                        "Adam, Stacey (FNIH) [T]"
                                                            (b) (6)
                 (b) (6)
                                                           "Alvarez, Rosa Maria"
                 "James, Stephanie (FNIH) [T]" < (b) (6)
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                        "Kim, Elizabeth" < (b) (6)
                                                           "Tolman, Brett"
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                       "Wachtel, Jonathan" <
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                                                 (b) (6)
                                                               Prabhavathi Fernandes
                               Rose Li <
                                                                Dana Carluccio
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                               "Lagos, Enrique (NIH/NCATS) [E]" < (b) (6)
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                                                                                       "Jonson.
<
                                           "Gonzalez, Nina" < (b) (6)
Samantha (NIH/NCATS) [E]" < (b) (6)
"Simon, D na (NIH/OD) [C]" < (b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" (b) (6)
            , "Rodriguez, Robin D" <
                                     (b) (6) Dave Frankowski
                                     "Baric, Toni C" <
<
                                                               (b) (6)
                                                                                 "Lowy, Douglas
                    (b) (6) Nancy Haigwood <
                                                                     "Stratton, Benjamin"
(NIH/NCI) [E]" <
                                                       (b) (6)
                       "Gadbois, Ellen (NIH/OD) [E]" < (b) (6)
                                                                         "Anderson, James
         (b) (6)
(NIH/OD) [E]" <
                       (b) (6)
                                                   (b) (6)
            (b) (6)
                               "Diamond, Michael" < (b) (6)
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Subject: RE: ACTIV Preclinical full working group

External Sender. Be aware of links, attachments and requests.

And convalescent plasma appears to block it as well as the G variant

Tony

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From: Florence, Clint (NIH/NIAID) [E] <
Sent: Wednesday, July 1, 2020 11:39 AM
To: Menetski, Joseph (FNIH) [T] <
                                              Hild, Sheri (NIH/OD) [E] <
                                                                             (b) (6)
                                   (b) (6)
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                                    Baric, Ralph
                                                      (b) (6)
           (b) (6) Ottinger, Elizabeth (NIH/NCATS [E] <
                                                                                     Colvis,
                                                                     (b) (6)
                              (b) (6) Hewitt, Judith (NIH/NIAID) [E] <
Christine (NIH/NCATS) [E] <
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Deming, Damon (FDA/CDER) <
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Parker, Ashley (NIH/OD) [E] <
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                                               Collins, Francis (NIH/OD) [E]
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                              Adams, Peter (OS/ASPR/BARDA) < (b) (6)
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                                                                                   Rao, Srinivas
                         Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar
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                          Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA)
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          (b) (6)
                          Punturieri, Antonello (NIH/NHLBI) [E] <
                                                                       (b) (6)
                                                                                       Charette.
          (b) (6)
Marc (NIH/NHLBI) [E] <
                                          Fessel, Josh (NIH/NHLBI) [E] < (b) (6)
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         (b) (6)
                         Frank.
Austin, Christopher (NIH/NCATS) [E] < (b) (6)
                                                      Melencio, Cheryl (FNIH) [T]
                    Colvis, Christine (NIH/NCATS) [E]
                                                           (b) (6)
                                                                          Desrosiers, Betsy
                         Hughes, Eric < (b) (6) Jansen, Kathrin
              (b) (6)
                          Kurilla, Michael (NIH/NCATS) [E] <michael.kurilla@nih.gov>; Lowy, Douglas
          (b) (6)
(NCI) < 
          (b) (6)
                    Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T]
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< (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) James, Stephanie (FNIH) [T] < Alvarez, Rosa Maria < (b) (6) (b) (6) Kim, Elizabeth < (b) (6) Tolman, Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes < (b) (6) Rose Li < Dana Carluccio < (b) (6) (b) (6) Lagos, Enrique (NIH/NCATS) [E] < Jonson, Samantha (NIH/NCATS) [E] (b) (6) Simon, Dina (NIH/OD) [C] Gonzalez, Nina < (b) (6) (b) (6) Burrus Shaw, Cyndi (NIH/OD) [E] < Rodriguez, Robin D (b) (6) (b) (6) < Dave Frankowski Baric, Toni C (b) (6) (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] < Florence, Clint (b) (6) Nancy Haigwood < Stratton, Benjamin (NIH/NIAID) [E] < (b) (6) (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < Annaliesa. (b) (6) Diamond, Michael (b) (6) (b) (6) Subject: Re: ACTIV Preclinical full working group All -U PITT's pre-print in YOUNG AGMs utilizes the Munich strain which I believe has the D614 mutant. In their hands, they didn't report any dramatic increase in pathogenesis with the assays they implemented. Might be of benefit in the EXE meeting tonight. Just an FYI. Clint From: (b) (6) When: 10:00 AM - 11:00 AM July 1, 2020 Subject: ACTIV Preclinical full working group Location: https://fnih.zoom.us (b)(6)Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom.u (b) (6) Meeting ID: (b) (6) Password: (b) (6) One tap mobile (b) (6) US (Germantown) US (Chicago) Dial by your location (b) (6) US (Germantown)

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Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] 6/1/2020 10:28:22 PM Mensah George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Vincent, Mike Bascles, Lione! Corey, Larry [(b) (6) (b) (6) (b) (6) Garner, Carlos [Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group] (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers , Betsy Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj); Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura Sizemore, Christine (NiH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d642Sf79-Peter.Stein); Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Kublin MD, MPH, James Ferguson, Sue (b) (6) Gadbois, El en (N H/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisef]; Chen, Jue (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40509dd20ea84f0eb23950b0b208440b-chenj19); (b) (6) (b) (6) (b) (6) (b) (6) Iturriaga, Erin (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65eb1f37c0a3421eb1186931e4cb5fb6-iturr ae]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Pearson, Gail (NIH/NHLB) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb1e26f1e264499aa898a482fe0b4045-pearsong), Lash, Tiffani (NIH/NIBIB) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b05d39abdd5401f982S2S36c598S269-baileyti); Merchak, Todd (NIH/NIBIB) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6cf5910b2ab445c80b8f1329ddc0387-merchaxt]; Wachtel, Jonathan Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Hughes, Eric Jansen, Kathrin Lowy, Douglas (NCI) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

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James, Stephan e (FNIH) [T] [/o=ExchangeLabs/ou=Exchange

Heaton, Penny [

(b) (6)

Dear Colleagues, Attached is the meeting agenda, we'll be welcoming the RADx team to this meeting and hearing about their activities. Best regards, Karen

CT Capacity working group members, Many thanks for all the hard work that you have put into meeting our ACTIV mandate – looking forward to operationalizing the outcomes of your efforts. Let's continue to meet regularly through the month of June (once a week) to continue to build out the inventories of CROs/SMOs/Networks/Sites and innovation/efficiencies, where needed, and, to integrate with other ACTIV working groups in support of protocol implementation (treatment and prevention). Best regards, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] 4/9/2020 5:28:03 PM Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bright, Rick Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Marks, Peter (FDA/C8ER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd); Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola}, Meeker, David Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYOIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Pangalos, Mene Pao, William [Paul, Steve (b) (6) (b) (6) (b) (6) Perlmutter, Roger [Plump, Andy [Rasi, Guido (b)(6)(b) (6) Reed, John Rouse, Doris [rouse@rti.org]; Santos, Michael (b) (6) (b) (6) (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr); Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tsaj, John]; Virgin, Skip [Vessey, Rupert (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John Parker, Ashley (NIH/OD) (E) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric [Jansen, Kathrin (b) (6) (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa] Barasch, Kimberly (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa); Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group]

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Kım, Elizabeth [(b) (6)	Wachtel, Jonath	an (b)	(6)	Tolman, Bret	t		
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Subject: ACTIV response partnership leadership team meeting #2 Location: https://zoom.us/ (b) (6)

Start: 4/22/2020 2:00:00 PM End: 4/22/2020 3:00:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bright, Rick; Collins, Francis (NIH/OD) [E]; Corey, Larry, Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael, Erbeiding, Emily (NIH/NIAID) [E], Fauci, Anthony (NIH/NIAID) [E]; James, Stephanie (FN H) [T]; Lane, Cliff (NIH/NIAID) [E], Marks, Peter (FDA/CBER); Marston, Hi ary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve, Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Stein, Peter (FDA/CDER); Stoffeis, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Parker, Ash ey (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Co vis, Christine (NIH/NCATS) [E], Desrosiers, Betsy; Hughes, Enc; Jansen, Kathrin; Kurilia, Michael (NIH/NCATS) [E], Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann, Thomas, Ashley (FDA/CDER), Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Li, Rose; Tountas, Karen (FNIH) [T]; Zottoli, Jessica; Gonzalez, Nina; Anderson, Margaret; Robert Plenge, Stratton, Ben; Alvarez, Rosa; Kim, Elizabeth; Wachtel, Jonathan; Tolman, Brett

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Melencio, Chery! (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC1 8/18/2020 3:11:23 PM Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane Carter, Kara (b) (6) Cavaleri, Marco (b) (6) Cihlar, Tomas [(b) (6) (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Admin strative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp], Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary,Disbro); Do sten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, H lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, .ohn (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola), Meeker, David Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh Pangalos, Mene [(b) (6) (b) (6) Pao, William Parker, Ashley (NiH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa9Saaaafe06ebd70-parkeras), Paul, Steve Perlmutter, Roger [Plenge, Robert [(b) (6) (b) (6) (b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group Plump, Andy [(b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo], Rasi, Guido Reed, John Reese, David [Rouse, Doris (b) (6) (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr}; Skovronsky, Daniel Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michaeli Tsai, John Vessey, Rupert [(b) (6) (b) (6) Virgin, Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] Skip [(b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom); Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash , Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy

(b) (6)

Zottoli, Jessica

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Subject:

ACTIV Leadership Call #9

Location: https://fnih.zoom.

(b) (6)

Start: End: 10/21/2020 4:00:00 PM 10/21/2020 5:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NiH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NiH/OD) [E]; Corey, Larry; Culp, Michelle (NiH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NiH/NiAID) [E]; Erck, Stan; Fauci, Anthony (NiH/NiAID) [E]; Gadbois, Ellen (NiH/OD) [E]; Gibbons, Gary (NiH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]. Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NiH/NiAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NiH/NiAID) [E] Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NiH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NiH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NiH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NiH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NiH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, He en; Elsaid, Olivia; Gonzaiez, Nina; Hawk, Harr son; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NiH/OD) [E]; Burklow, John (NiH/OD) [E], Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NiH/OD) [E]; Myles, Renate (NiH/OD) [E]; Wolinetz, Carrie (NiH/OD) [E]

Optional Attendees:

Austin, Sarah (NIH/NIAID) [E], Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NiH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorg, Sara, Hoban, Michelle; Hoffstetter, Renata (FNIH) [T], Iberdemaj, Vaide; Jenkins, Christine S; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan, McManus, Ayanna (NIH/OD) [E]; Minnich, Beth, Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy, Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From:

Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent:

4/6/2021 6:35:17 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-col(insf]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject:

RE: Speaking to ACTIV-2 today

Hi Francis,

My apologies for the late arrival in your inbox.

Please find below some suggested thoughts for your presentation in 30 minutes. Feel free to any that you feel are appropriate. I think the main point that the team was hoping for is just a strong show of NiH support from the top for all the efforts the sites have been putting in.

Please feel free to revise if needed:

- Appreciate all the dedication, hard work, and long hours contributed to ACTIV-2
- Understand that there have been many challenges to overcome:
 - Challenging routes of drug administration IV infusions for mAbs
 - Rapid pace of the master protocol for site stand up and regulatory approvals
 - Fast addition of new agents causing continuous updates at the sites
 - o THANK YOU for your perseverance through all of these
- Congratulations on creating a vast and diverse network to reach patients where they are:
 - Over 150 sites open domestically and 100+ international sites ready to come onboard
 - Successful branding and promotional campaign
 - Continued dedication to reaching underserved communities: Successful deployment of the "Barber Shop" program and others
- Agents being tested are making a difference:
 - Over 1200 patients treated with Lilly's bamlanivimab EUA authorized agent
 - Brii Bio advancing to Phase 3 testing
 - Bril Bio and AZ mAb cocktails and SAB polyclonal Abs seem to retain potency against the emerging variants of concern

Strong desire and collaborative spirit to share what you have learned with other trials to help advance the field

Thanks, Stacey Stacey J. Adam, PhD Associate Vice President Research Partnerships

Direct: (b) (6) | Mobile: (b) (6)

From: Collins, Francis (NIH/OD) [E] < (b) (6)

Sent: Tuesday, April 6, 2021 8:17 AM

To: Adam, Stacey (FNIH) [T] < (b) (6) Wholley, David (FNIH) [T] < (b) (6)

Subject: Speaking to ACTIV-2 today

Hi Stacey and David,

My calendar says I am speaking to the ACTIV-2 PIs today at 3 pm. I think this was supposed to be a "rally the troops" moment, thanking them for their hard work and encouraging continuing efforts. Can you suggest some specific points I should make with these folks?

Thanks, Francis

Melencio, Chery! (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 10/15/2020 4:56:47 PM Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane Carter, Kara Cavaleri, Marco (b) (6) (b) (6) Cihlar, Tomas []; Collins, Francis (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro); Do sten, Mikael (b) (6) Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldinger]; Erck, Stan Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel); Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert, John]; Kramer, Lynn Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-danel; Lepore, John Marks, Peter (FDA/C8ER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, H.lary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola); Meeker, David]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijpl; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh Pangalos, Mene [Pao, William (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras); Paul, Steve Perimutter, Roger [Plenge, Robert [(b) (6) (b) (6) (b) (6) Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group Plump, Andy [(b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido Reed, John Reese, David [Rouse, Doris (b) (6) (b) (6) (b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Talley, Michael Tsai, John ; Vessey, Rupert [Virgin, (b) (6) (b) (6) (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd], Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc}; Young, John Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy

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Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom); Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs); Togash, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy Zottoli, Jessica nan (b)(6)Regan, Donna M (b)(6)Hamilton, Nancy [Dana Carluccio (b)(6)(b) (6) (b)(6)(b)(6)Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

Subject: ACTIV Leadership Call #9
Location: https://fnih.zoom.us/ (b) (6)

Start: 10/21/2020 1:15:00 PM **End:** 10/21/2020 2:15:00 PM

Show Time As: Tentative

Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T], Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ash ey (NIH/OD) [E], Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras., Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul, Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip, Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER). Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin, Kurilla, Michael (NIH/NCATS) [E], Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, He en; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harr son; Stratton, Ben, Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (b) (6) (NIH/OD) [E]; Myles, Renate (NIH/OD) [E], Wolinetz, Carrie (NIH/OD) [E], Appell, Evan; Sorosa, Alex; Connelly, Sarah

Optional Attendees:

Austin, Sarah (NIH/NIAID) [E], Barasch, Kimberly (NIH/NIAID) [C], Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E], Carver, Trea (NIH) [C]; Caulfied, Anita, Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara, Hoban, Michelle, Hoffstetter, Renata (FNIH) [T], Iberdemaj, Vaide; Jenkins, Christine S., Krack, Kimberly, Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan, McManus, Ayanna (NIH/OD) E]; Minnich, Beth, Perala, Mie; Protasiewicz, Ann, Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Regan, Donna M; Hamilton, Nancy; Dana Carluccio; dee.iowings@astrazeneca.com; Lowy, Douglas (NIH/NCI) [E]

Due to an unavoidable conflict for Dr. Collins, it is necessary to move this call from 12:00 p.m. to 9:15 a.m. Thank you.

Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

11/19/2020 5:07:19 AM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC:

Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Menetski, Joseph (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

Subject:

FW: ACTIV Leadership mtng Thurs 12-1pm Attachments: ACTIV.leadership.transmission.trial.11 20 pptx

Just fyi, what will be added to the slides shown tomorrow.

From: Santos, Michael (FNIH) [T] < Sent: Wednesday, November 18, 2020 9:19 PM

To: Appell, Evan <

(b) (6)

Cc: Gonzalez, Nina <

(b) (6)

Wholley, David (FNIH) [T] <

Subject: FW: ACTIV Leadership mtng Thurs 12-1pm

Hi Evan,

Doug made two slides to discuss the transmission study. Would you mind slotting them in behind the two existing vaccine slides in the version of the deck that will be presented?

Unsurprisingly Doug used a different slide template, but I already let him know the font, colors, etc. would likely be converted to match the rest of the deck, so feel free to make formatting adjustments as desired.

The slides are text-heavy but we don't really have time to iterate (and I think they explain the key points well).

Thanks,

Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] < (b) (6) Sent: Wednesday, November 18, 2020 8:43 PM

To: Santos, Michae (FNIH) [T] <

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

(b) (6)

btolman <

(b) (6)

Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: I ended up making two slides about the proposed protocol (attached). Please get in touch with me if you have concerns/suggestions. Thanks, Doug

From: "Santos, Michael (FNIH) [T]" < (b) (6)

Date: Wednesday, November 18, 2020 at 3:02 PM

To: "Lowy, Douglas (NIH/NCI) [E]" < (b) (6)

Cc: Maureen Johnson < (b) (6) "Kozlowski, Mary (NIH/NCI) [C]"

< (b) (6) (b) (6) **Subject:** RE: ACTIV Leadership mtng Thurs 12-1pm

HI Doug,

Great. Those changes will go into the existing slides and go out in the pre-read. If you send your additional slide any time before the meeting, that will be added to the presentation deck.

If it's helpful, I've attached the slides from today's meeting.

Thanks, Mike

Michael Santos, PhD

Associate Vice President, Science Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] < (b) (6)

Sent: Wednesday, November 18, 2020 2:13 PM

To: Santos, Michae (FNIH) [T] < (b) (6)

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

< (b) (6) (b) (6)

Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike,

Thanks for the new slide. Please add "Some" to the left ("Some previous...") and right sides ("Some key points...") of the new slide.

The phase 2b proposal is terrific. I would like to have a slide for it as well. I can make one later, but not right now.

Doug

From: "Santos, Michael (FNIH) [T]" < (b) (6)

Date: Wednesday, November 18, 2020 at 11:44 AM

To: "Lowy, Douglas (NIH/NCI) [E]" < (b) (6)

Cc: Maureen Johnson < (b) (6) "Kozlowski, Mary (NIH/NCI) [C]"

(b) (6) (b) (6)

Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

Francis asked for an addition slide reminding the group of some of the previous topics that the WG/SG have discussed (prompted because he asked about some additional topics, like pediatrics, that I mentioned that we previously met to discuss).

Attached is the updated set of 2 slides for tomorrow. The first slide shouldn't be too controversial, and you can of course add color from those previous conversations if you'd like.

Thanks, Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Tuesday, November 17, 2020 10:07 AM **To:** Lowy, Douglas (NIH/NCI) [E] < (b) (6)

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

< (b) (6) (b) (6)

Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Great.

I was moving over the weekend and yesterday, so I didn't actually get to my computer for work until 1am. The slide only took a few minutes, so no problem at all.

Thanks, Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] < (b) (6)

Sent: Tuesday, November 17, 2020 10:05 AM

To: Santos, Michael (FNIH) [T] < (b) (6)

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

< (b) (6) (b) (6)

Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: Thanks, but sorry you needed to be up at 2 AM to do this! The slide looks fine. Doug

From: "Santos, Michael (FNIH) [T]" < (b) (6)

Date: Tuesday, November 17, 2020 at 2:01 AM

To: "Lowy, Douglas (NIH/NCI) [E]" < (b) (6)

Cc: Maureen Johnson < (b) (6) "Kozlowski, Mary (NIH/NCI) [C]"

< (b) (6) (b) (6)

Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

Here's a draft slide for the meeting Thursday. If you'd like any changes, I have until afternoon to make them.

You're currently on the agenda for 12:45-12:55, so it's plausible that you'll end up with less than 10 mins. By Thursday there will be both last week's WG meeting and tomorrow's VCT Sub-Group meeting to report on.

Thanks, Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Monday, November 16, 2020 10.56 AM **To:** Lowy, Douglas (NIH/NCI) [E] < (b) (6)

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

(b) (6) (b) (6) (b) (6)

Subject: RE: ACTIV Leadership mtng Thurs 12-1pm

Great. Thanks, Doug!

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NiH/NCI) [E] < (b) (6)

Sent: Monday, November 16, 2020 10 56 AM

To: Santos, Michae (FNIH) [T] < (b) (6)

Cc: Johnson, Maureen (NIH/NCI) [E] < (b) (6) Kozlowski, Mary (NIH/NCI) [C]

< (b) (6) (b) (6)

Subject: Re: ACTIV Leadership mtng Thurs 12-1pm

Hi Mike: I can do it. Thanks for the slides! (FYI: I have a conflict, but the ACTIV meeting is the higher priority.) Doug

From: "Santos, Michael (FNIH) [T]" < (b) (6)

Date: Monday, November 16, 2020 at 10:53 AM

To: "Lowy, Douglas (NIH/NCI) [E]" < (b) (6)

Cc: Maureen Johnson < (b) (6) "Kozlowski, Mary (NIH/NCI) [C]"

< (b) (6) (b) (6)

Subject: ACTIV Leadership mtng Thurs 12-1pm

Hi Doug,

We've been asked to give a 10-min update on the Vaccines WG at the next ACTIV Leadership meeting, Thursday, 12-1pm.

Are you able to attend? I'll make a slide summarizing the last WG mtng (and by then the Clinical Trials Sub-Group meeting Wednesday will have happened). If you're not available, I can ask Kathrin, but given that she wasn't there last week it might be tougher for her to represent the conversation.

Thanks,

Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) fnih org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID 19 fnin.org/pandemic



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

9/23/2020 2:15:18 PM

To:

Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5)

CC:

Collins, Francis (NIH/OD) [£] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject:

FW: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Further clarification on the question just sent.

From: Pao, William <

(b) (6)

Sent: Wednesday, September 23, 2020 10:12 AM

To: Wholley, David (FNIH) [T] < (b) (6)

Subject: RE: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Sorry - to clarify - we know there's a shortage of testing.

I mean testing of patients who are getting pneumonia specifically.

From: William Pao

(b) (6)

Sent: Wednesday, September 23, 2020 4.04 PM To: 'Wholley, David (FNIH) [T]' (b) (6)

Subject: RE: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING

Hi David.

Very informative meeting as usual.

I had a question maybe not related to ACTIV activities but to OWS or CDC. However, if addressed could help with recruitment on ACTIV studies.

I noticed on this CDC link that the number of deaths related to COVID-19, pneumonia, or influenza for 2020 are nearly 300,000, while the number attributed to COVID-19 only are almost 200,000,

https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm

To me, this suggests many patients still are just not getting tested. Is someone in the government addressing this? If addressed, maybe there'd be more patients to enroll in trials?

Best,

William

From: Melencio, Cheryl (FNIH) [T] > On Behalf Of Wholley, David (FNIH) [T] (b) (6) Sent: Wednesday, September 23, 2020 2:35 AM To: Austin, Christopher (NIH/NCATS) [E] >; Bancel, Stephane (b) (6) Carter, Kara (b) (6) n>; Cavaleri, Marco (b) (6) Cihlar, Tomas < Collins, Francis (NIH/OD) [E] (b) (6) (b)(6). Culp, Michelle (NIH/OD) [E] < Corey, Larry (b) (6) (b)(6)(b)(6)Disbrow, Gary (OS/ASPR/BARDA) (b) (6) ; Dolsten, Mikael >; Erbelding, (b) (6) Erck, Stan Emily (NIH/NIAID) [E] (b) (6) (b) (6) >; Fauci, Anthony (NiH/NIAID) [E] >; Freire, Maria (FNIH) [T] Gadbois, Ellen (NIH/OD) [E] (b) (6) (b) (6) . Gibbons, Gary (NIH/NHLBI) [E] >; Hudson, Thomas (b) (6) (b) (6) >; James, Stephanie (FNIH) [T] >; Johnson, Robert (OS/ASPR/BARDA) (b) (6) (b) (6) ; Lane, Cliff (NIH/NIAID) [E] < >; Kramer, Lynn (b) (6) (b) (6) (b) (6) ; Marks, Peter (FDA/CBER) Lepore, John (b) (6) >; Marston, Hilary

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Plenge, Robert <
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Chen, Helen Q.
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Menetski, Joseph (FNIH) [T]
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Subject: Materials for September 23 ACTIV Partnership Leadership Team Teleconference TOMORROW MORNING
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Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 9:00 – 10:00 AM Eastern U.S. time tomorrow, Wednesday September 23. I have also attached notes from our August 26 Leadership Team meeting as well as our last ACTIV EC meeting on September 9.

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Find your local number: https://fnih.zoom (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

On erg

11400 Rockville Pike Suite 600 North Bethesda, MD 2085?

In 2019, the FNIH carned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOCI Sent: 7/21/2020 7:14:01 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) Disbrow, Gary (OS/ASPR/BARDA) [Dolsten, Mikael (b) (6) (b) (6) Gibbons, Gary (NIH/NHLBI) [E] [Marks, Peter (FDA/CBER) (b) (6) (b) (6) Pao, William [Stoffels, Paul (b) (6) (b) (6) (b) (6) Woodcock, Janet (FDA/CDER) [Colvis, Christine (NIH/NCATS) [E] (b) (6) (b) (6) Desrosiers, Betsy [(b) (6) **Eric Hughes** Jansen, Kathrin [Kurilla, Michael (NIH/NCATS) [E] (b) (6) (b) (6) Read, Sarah (NIH/NIAID) [E] Lowy, Douglas (NCI) [(b) (6) (b) (6) Young, John ! Fauci, Anthony (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Plump, Andrew (b) (6) CC: Adam, Stacey (FNIH) [T] [Alvarez, Rosa [Anderson, Margaret (b) (6) (b) (6) Chen, Helen [Elsaid, Olivia [(b) (6) (b) (6) (b) (6) Gonzalez, Nina James, Stephanie (FNIH) [T]]; Menetski, Joseph (FNIH) (b) (6) [T] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stratton, Benjamin Tolman, Brett [Tountas, Karen (FNIH) [T] (b) (6) (b) (6) (b) (6)]; Wholley, David (FNIH) [T] Wachtel, Jonathan [; Anderson, James (b) (6) (b) (6) Austin, Christopher (NIH/NCATS) [E] [(NIH/OD) [E] [Burklow, (b)(6)(b) (6) John (NIH/OD) [E] [Castillejos, Carlos Culp, Michelle (NIH/OD) [E] (b) (6) (b) (6) (b) (6) FNIH Central Account [(b) (6) Gadbois, Ellen (NIH/OD) [E] Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lane, Cliff (NIH/NIAID) [E] (b) (6) Myles, Renate (NIH/OD) [E] [Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6) Carver, Trea (NIH) [C] [(b) (6)]; Lagos, Enrique (NIH/NCATS) [E] Simon, Dina (NIH/OD) [C] (b) (6)]; Sepulveda, Dorina (FNIH) [T] [(b) (6) Gorman, Greta (FNIH) [T] [(b) (6) Meltzer, Abbey (FNIH) [T] (b) (6)]; Conrad, Patricia (NIH/NIAID) Barasch, Kimberly (NIH/NIAID) [C] (b) (6) (b) (6) [E] [Dimishkov, Roxanne (NIH/NHLBI) [C] []; McManus, (b) (6) (b) (6) Ayanna (NIH/OD) [E] [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann Thomas, Ashley (FDA/CDER) Riccobene, Kim [(b) (6) (b) (6) (b) (6) Wood, Gretchen (NIH/OD) [E] | (b) (6) Togashi, Mieko (NIH/NCI) [E]]; Underwood, Nancy [Zottoli, Jessica (b) (6) (b) (6) Lowy, Douglas (NIH/NCI) [E] [Hawk, Harrison (b) (6) (b) (6) Lucas Smalldon Wolinetz, Carrie (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Hardesty, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs) Subject: **ACTIV EC & Working Group Co-Chair Meeting** Location: https://fnih.zoom.us/ (b) (6) Start: 8/14/2020 4:00:00 PM End: 8/14/2020 5:00:00 PM Show Time As: Busy

Attendees: Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock,

Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E];

Required

Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Optional Attendees:

Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hardesty, Rebecca (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Hawk, Harrison; Lucas Smalldon

Shortening calls to 1 hour in length.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] Sent: 7/13/2020 11:21:01 PM To: Bascles, Lionel Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry ; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein); Takas, Therese Vincent, Mike Weinmann, Gail (NIH/NHLBI) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang); Stratton, Ben CC: Wachtel, Jonathan [(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [Jansen, Kathrin Lowy, Douglas (NCI) (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John (b) (6) Ardiff, Bernadette (b) (6) Criffield, Robin Hamilton, Nancy [Melencio, Cheryl (FNIH) [T] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth [bminnich@fredhutch.org]; Mueller-Reichenstein, Petra [(b) (6) (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Heaton, Penny (b) (6)